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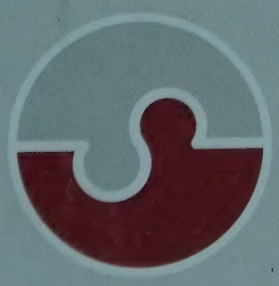
Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

Sri Lanka



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Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

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Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Sri Lanka

by Karen Caines and Palitha Abeykoon

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Foreword

by Roy Widdus, Ph.D.
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Global Forum for Health Research

The study described in this report is one of a series initiated and designed by the Initiative on Public-Private Partnerships for Health (IPPPH), supported principally by the UK Department for International Development, and undertaken in association with the Institute for Health Sector Development based in London. The series also includes country studies on Uganda (the pilot country studied in 2003), Botswana and Zambia. A 'Synthesis Report' covers conclusions and recommendations across all countries and programmes evaluated.

IPPPH was established in 2000, in part to develop a solid evidence base on public-private 'partnerships' for health so that the benefits of such collaboration for populations afflicted by poverty could be maximized and potential risks ameliorated.

IPPPH identified early in its existence the need for the type of study described in this report in response to a range of questions being raised about 'partnerships' addressing drug access in low-and middle-income countries that included donations or discounted pricing from pharmaceutical companies. Funding was provided by the UK Department for International Development (DFID) with supplementary support from the general contributors to IPPPH, namely, the Bill & Melinda Gates Foundation, the Global Forum for Health Research, The Rockefeller Foundation, and the World Bank.

The study design benefited from wide input, including staff of the World Health Organization and the Study Advisory Committee. A team of consultants was selected with assistance from the Institute for Health Sector Development, London, an organization specializing in evaluation of health systems issues in developing countries. Ultimate approval of the study protocol rested necessarily with the IPPPH as the agent responsible to the principal funder, DFID, along with the national government counterpart.

All members of the consultant team are independent of the pharmaceutical industry and IPPPH. None of the national consultants had any direct programmatic or managerial responsibility for any of the programmes examined. However, their knowledge of the national health system and key information sources greatly benefited the study.

The IPPPH Secretariat, along with the Study Advisory Committee, offered suggestions for clarification of the draft text of the report and is pleased to publish the consultant team's final report in its entirety, as a significant contribution to understanding the actual impact at national and field level of these diverse collaborative ventures.

This study can stand alone but is part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access to pharmaceuticals for those affected by diseases associated with poverty. However, as noted above, it is part of a series undertaken to serve this general goal. Readers should consult the 'Synthesis Report'[1] for general conclusions on those issues addressed in this series of studies. This series of studies adds considerably to the evidence base on 'access' public-private partnerships but further issues need to be considered. The Foreward of the Synthesis Report identifies some programmes and issues that this series of studies could not cover.

IPPPH thanks the UK Department for International Development for its financial support, and the excellent consultant team, Karen Caines, consultant, Institute for Health Sector Development, United Kingdom – who deserves particular credit as team leader for the study – and Palitha Abeykoon, member of the Sri Lankan National Health Advisory Council, Sri Lanka.

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[1] *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Selected Low and Middle income Countries: A Synthesis Report from Studies in Botswana, Sri Lanka, Uganda and Zambia*; ISBN 2-940286-21-3.

Special thanks must go to the many individuals in Sri Lanka who gave generously of their time to the consultant team. We trust the insights of the study, especially into areas needing more external technical and financial assistance, will prove useful to them, as well as the broader international community.

Abbreviations

AFC	Sri Lanka Government's Anti Filariasis Campaign
ALC	Sri Lanka Government's Anti Leprosy Campaign
DEC	Diethylcarbamazine
GAEL	Global Alliance for the Elimination of Leprosy
GAELF	Global Alliance to Eliminate Lymphatic Filariasis
GFATM	Global Fund to Fight AIDS, TB and Malaria
GDF	Global Drug Facility
GOSL	Government of Sri Lanka
GSK	GlaxoSmithKline
HMIS	Health Management Information System
IPPPH	Initiative on Public-Private Partnerships for Health
LF	Lymphatic Filariasis
MB	Multibacillary leprosy
MDA	Mass drug administration
MDT	Multi-drug therapy
MIS	Management Information System
MOH	Ministry of Health
MSD	Medical Supplies Division
NFSD	Novartis Foundation for Sustainable Development
NGO	Non governmental organisation
PB	Paucibacillary leprosy
PHI	Public health inspector
PPP	Public-private partnership
PRSP	Poverty Reduction Strategy Paper
SEARO	WHO's South-east Asia regional office
SPC	State Pharmaceutical Corporation
SWAp	Sector-wide Approach
TAG	WHO's Technical Advisory Group for the Elimination of Leprosy
TB	Tuberculosis
WHA	World Health Assembly
WHO	World Health Organization
WR	WHO Representative in Sri Lanka

Executive summary

The UK Department for International Development (DFID) has funded the Initiative on Public-Private Partnerships for Health (IPPPH – part of the Global Forum for Health Research), in association with the Institute for Health Sector Development, to conduct four country studies – in Botswana, Sri Lanka, Uganda and Zambia – to assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals. The specific remit is to examine issues of ownership, integration, coordination, implementation and impact. A key question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates better drug availability and access by the poor. Further questions include whether the availability of free drugs distorts decisions on priorities or prices, and the feasibility and sustainability of taking such initiatives to scale.

This study in Sri Lanka examined Novartis' donation of multi-drug therapy (MDT) for individual treatment of leprosy patients, and GlaxoSmithKline's (GSK) donation of albendazole for community mass drug administration to break the transmission of lymphatic filariasis (LF). These drug donations relate to wider disease-focused global partnerships and WHO's own leprosy and LF elimination programmes. The study also reviewed the substantial support for the Sri Lankan Government's Anti Leprosy Campaign (ALC) provided by the Novartis Foundation for Sustainable Development (NFSD) since 1988. It additionally considered whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

In 2001 Sri Lanka had an estimated population of 18.7 million, with an annual average growth rate of 1.1%. Sri Lanka's social indicators are impressive for a low-income country with a per capita income of around US$ 850 (average for the last decade). It has a high level of attainment in the Human Development Index (0.711), adult literacy of 90%, an infant mortality rate of 12.2 per 1000 live births, and life expectancy at birth of 75 years for females and 71 for males. The gender development index is well above the average for developing countries.

Key study conclusions are as follows

- There was complete unanimity among interviewees in Sri Lanka that the drug donation partnerships have materially assisted the national leprosy and LF elimination programmes. The key benefit is that they provide a sustained and high quality supply of effective and user-friendly drugs which the government of Sri Lanka would otherwise struggle to afford. Given the nature of the diseases, high levels of programme coverage and the fact that the drugs are provided free and in unlimited amounts to recipients, the donations are likely to have assisted access to such drugs by the poor.

- Both donated drugs are seen as user-friendly. There is an ancillary benefit of mass administration of albendazole in its action as an anti-helminthic. Current MDT blister packs for leprosy are highly regarded for enhancing compliance and reducing the risk of development of resistance. Novartis' responsiveness to local problems (e.g. donation of clofazamine alone for severe reactions) is appreciated.

- Both elimination programmes were long-standing government campaigns, considerably pre-dating the drug donations. There is no evidence of skewed priorities or diversion of scarce human and financial resources at either central or provincial levels, as a result of the drug access PPPs.

- Both programmes are running at full national scale, subject only to challenges caused by the recent long-term conflict in the North East which are now being addressed intensively. The Anti-

Leprosy Campaign is prioritising action in the North East.

■ The donated drugs have little commercial value and the issue of prices does not arise significantly, though local commercial sales of albendazole as an anti-helminthic have fallen following the free mass drug administration of albendazole for LF.

■ From the country perspective, there appears to be no evident direct commercial benefit for Novartis or GSK from the drug donations, or indeed from the wider support provided by the Novartis Foundation for Sustainable Development. A supporting study at global level suggests that any benefit relates to generalised corporate public relations, better relations with governments and improved staff morale.

■ There has been no formal evaluation of NFSD's 15-year support for the Anti Leprosy Campaign, amounting in cash to about US$1.7 million excluding the unquantified cost of drugs. NFSD's involvement in Sri Lanka is perceived as "a singular success story": immensely supportive but not directive, providing real benefit and external stimulus. It has helped raise awareness, motivated and facilitated active staff engagement, and contributed to innovation in leprosy control. Partnership working appears to have been excellent. National partners perceive no downsides.

■ NFSD support has been especially successful because it is not just a vertical drug donation, but part of a much broader programmatic approach. For example, without external support for an extensive social marketing campaign, the Anti-Leprosy Campaign is unlikely to have been so successful in flushing out new cases or reducing stigma.

■ NFSD financial support was significant but fell short of flooding the system with money which would probably have had a non-sustainable effect on the programme and a deleterious effect on other programmes.

■ The NFSD approach is felt to have helped develop a better understanding of management techniques among Sri Lankan partners. The Sri Lankan experience suggests that there is scope, perhaps through foundations particularly, for the successful application of more commercially-oriented practices such as social marketing.

■ Credit for success must also go to national partners. Government machinery has not micro-managed the leprosy and LF campaigns, both of which have benefited from able and committed leadership over time, and from wider partnerships in the country (e.g. with Universities, and the Department of Traditional Medicine).

■ Successful approaches in the Anti Leprosy Campaign provide lessons for other parts of the Sri Lankan health service particularly in terms of social marketing and of approaches to record-keeping and analysis, including software development. Lessons about stigma and compliance are particularly relevant to TB which is seeking to build on the leprosy experience.

■ The NFSD-supported integration of leprosy services into general health services posed major planning, operational and human change management challenges. It has so far been a positive experience in Sri Lanka; expertise has been developed at district level, effective networks have been created, and patients have more choice and easier access. Even before integration, because of issues around stigma, the Anti Leprosy Campaign strategy was based on trying to motivate people to come for treatment rather than case finding and pursuit.

■ Diseases that can be 'eliminated' as major public health problems are good choices for health commodity-focused PPP support because of their time-limited nature, thus minimising the risk of creating a dependency relationship and unsustainable programmes. In the case of NFSD's support for leprosy elimination over and above Novartis' continued supply of MDT, there is need for a realistic exit strategy that will meet the expectations of the people concerned and the requirements of the programme. Both partners regard the prospects of a smooth exit and a sustainable maintenance programme as good.

■ NFSD is unlikely to replicate its very intensive involvement in the Sri Lankan Anti Leprosy Campaign in more than a very few countries because of the substantial human, financial and other resource costs involved. But WHO Geneva confirms the view that innovative approaches developed in Sri Lanka with NFSD support were trend-setting and paved the way for solutions that have been adopted by many countries.

■ The study team has concluded that Sri Lanka would not be eligible for, nor benefit from, the other current drug access PPPs for tropical diseases. Funding for anti-retrovirals in an HIV/AIDS programme starting in July 2004 is being provided by a World Bank grant.

■ There is a strong case for Sri Lanka to make an application for free anti-TB drugs from the Stop TB Partnership's Global Drug Facility (GDF).[1] Because of the synergies with leprosy, NFSD has made clear its intention to offer the Sri Lankan Department of Health Services a package of support for social marketing, training etc, under its drug donation agreement with WHO, if the government successfully applies to the GDF. The availability of donated drugs and the offer of wider support are both likely to be of real benefit to Sri Lanka.

[1] An application was subsequently made to the GDF in August 2004.

1. Background and approach to the study

Background

In a vicious cycle, poverty is a major cause of health inequity in developing countries, and ill-health perpetuates poverty. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled by the public sector or NGOs independently.

In recent years, a number of public-private partnerships (PPPs) have been established to tackle particular health problems. They are usually targeted at specific products, diseases or technologies. One group of PPPs addresses access to pharmaceuticals critical to treatment or control of diseases disproportionately or uniquely affecting the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated or heavily discounted (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications.

These drug access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis and sleeping sickness) as compared with HIV/AIDS, tuberculosis and malaria which have attracted global attention. They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide.

However, they raise a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key question concerns the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates better drug availability and access by the poor. Further questions include whether the availability of free or reduced price drugs distorts decisions on priorities or prices, and the feasibility and sustainability of taking such initiatives to scale. This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of debt relief, Sector-Wide Approaches (SWAps) in health, and multisectoral Poverty Reduction Strategic Plans (PRSPs). Issues of integration, coordination, implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

The UK Department for International Development (DFID) has funded the Initiative on Public-Private Partnerships for Health (IPPPH – part of the Global Forum for Health Research), in association with the Institute for Health Sector Development, to conduct a series of studies across a range of access partnerships and countries. Following a pilot study in 2003 in Uganda, three further studies are being undertaken in 2004 in Botswana, Sri Lanka and Zambia. These studies can each stand alone but will also be analysed as a group. They are part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access to pharmaceuticals for those disadvantaged by poverty.

The study in Sri Lanka

Key issues for examination have included:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.

Sri Lanka Study
Key Terms of Reference

To assess the health and health systems impact in Sri Lanka of public-private partnerships for improving access to pharmaceuticals in relation to leprosy and lymphatic filariasis, examining issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured.

To assess whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available on the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and MIS/HMIS; government-NGO working relationships.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

Approach to the study

The study was undertaken in Sri Lanka in March 2004 by Karen Caines (study team leader), Institute for Health Sector Development, London and Dr Palitha Abeykoon, member of the Sri Lankan National Health Advisory Council. Both members of the study team are independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry.

In line with the views of a technical consultation meeting held in January 2003 to advise on study design, this was a rapid and largely qualitative study making extensive use of semi-structured interviews with key informants. Limitations on funding and time precluded original data-gathering.

The study team:

- Analysed global, national and district programme strategies, plans and reports, together with wider literature.
- Within the Sri Lanka Ministry of Health's Department of Health Services, interviewed the Director General of Health Services, the Deputy Director for Laboratory Services, the Director of the Anti Filariasis Campaign, the Director of the Anti Leprosy Campaign, the Director and Senior Pharmacist of Medical Supplies Division, and staff in the HIV/AIDS, TB and malaria programmes.
- Visited two districts in Sri Lanka – Gampaha and Kandy – selected on the basis of active implementation of the PPP programmes, ensuring that each programme was visited in at least one district; provincial representation; and security and accessibility within the timescale of the study.
- Interviewed a range of partners and stakeholders in Sri Lanka, including representatives of WHO, DFID, Ciba-Geigy/Novartis and GSK.
- At SEARO spoke to the Medical Officer for Leprosy and at WHO Geneva, interviewed the Director of the Department of Control, Prevention and Eradication in the Communicable Diseases Department, and the WHO Group Leader Leprosy Elimination. Unfortunately, the Lymphatic Filariasis team was not available at the time.

A list of interviewees is in Annex 2.

Acknowledgements

This study was completed with the willing and unstinted cooperation that the team received from everyone who was contacted or interviewed in Sri Lanka and Geneva. The team wishes to acknowledge in particular the support received from the staff of the Ministry of Health, both at the central and provincial levels, the universities and the private sector in Sri Lanka. Much assistance was also received from DFID and WHO at all levels. In particular, the staff of the WHO Office in Colombo took pains to ensure that the stay and the work were extremely pleasant and convenient. The authors thank all for their kindness and help.

2. Health challenges and the health system in Sri Lanka

The country context

Socio-economic characteristics

In 2001, Sri Lanka had an estimated population of 18.7 million, with an annual average growth rate of 1.1%.

Sri Lanka's social indicators are impressive for a low-income country with a per capita income of around US$ 850 (average for the last decade). It has a high level of attainment in the Human Development Index (0.711), an adult literacy of 90%, an infant mortality rate of 12.2 per 1000 live births, and life expectancy at birth of 75 years for females and 71 for males. The gender development index is well above the average for developing countries.

In large measure, these successes stem from social welfare programmes, introduced in the 1940s, which include the expansion of health and education services. However, since the 1970s, successive governments have found it increasingly difficult to maintain these services at an acceptable level of quality in the face of adverse economic conditions, structural adjustment programmes in the 1980s, 20 years of ethnic conflict in the north and east, and recent persistent droughts. Many households have become destitute or insolvent. About 80% of the poor reside in rural areas, compared with 8% in urban areas and 4% in the estate areas.[1] While Sri Lanka has been successful by international standards in targeting state funds to poorer groups, significant gaps remain.

The health sector figured prominently in the country's Poverty Reduction Strategy Paper (PRSP) which reaffirmed a policy of universal health services for all citizens. The PRSP pointed the way to measures aimed at overcoming regional disparities in access, rationalising health investments and services, encouraging the adoption of health insurance and strengthening hospital-based management systems. More recently the Sri Lankan Government has completed a review of reforms, which seeks to provide guidance for public action designed to achieve high economic growth and preserve the equity the country has been known for. Among other things, it aims at strengthening governance and improving health status.

Epidemiological information

Given rapid ageing of the population and success in combating the major communicable diseases, the disease burden in Sri Lanka has started shifting swiftly towards non-communicable diseases including mental health, accidents and injuries. The leading causes of death (by percentage of total mortality for year 2000[2]) are ischaemic heart disease (10.6%), diseases of the intestinal tract (9.3%), cerebrovascular disease (9.0%), pulmonary heart disease and diseases of the pulmonary circulation (8.6%) and neoplasms (7.5%). In 1996, during the conflict, violence (accidents, suicides and homicides) accounted for 22% of deaths. There are significant epidemiological variations between and within provinces, particularly in the conflict-affected areas and the tea estates.

While new problems are emerging, some health problems of the last century remain at alarming levels. The maternal anaemia rate remains at 35% and childhood malnutrition is still thought to be as high as 29% in under-fives – a figure which sits uncomfortably alongside Sri Lanka's significant reduction in infant mortality rates.

Malaria remains significant, and potentially serious. However, more than 50% of cases are in the North East and with the restoration there of anti-malarial activities such as treatment, improved surveillance, use of bednets and selective spraying services, the incidence is likely to reduce further over the next few years. Dengue and tuberculosis also pose significant risks. HIV/AIDS is a totally new challenge.

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[1] WHO Country Cooperation Strategy Sri Lanka 2002–2005, WHO, 2002

[2] National Health Bulletin 2000

Table 1. Health indices for Sri Lanka

	1995	2001 (provisional)
Life expectancy (at birth)	69.5 M 74.2 F*	70.7 M 75.4 F*
Infant Mortality Rate (IMR)	16.5 *	12.2 *
Under-five Mortality Rate	0.09 *	Not available
Maternal Mortality Ratio (MMR)	2.4 **	4.69†
Total Fertility Rate (TFR)	2.3 (1993)	1.9 (2000)
Contraceptive Prevalence Rate (CPR)	65%††	70% (2000)††
Access to safe water	68%*	75% *
Literacy Rate	90.1*	90.1*

Sources
* Annual Health Bulletin, Ministry of Health
† Population Division
** Family Health Bureau data bank
†† Director General of Health Annual Report

Prevalence is still low, the total of known HIV-positives in the country being less than 400, and there is a window of opportunity to ensure that it remains so.

The health system in Sri Lanka

Politico-administrative structure

Sri Lanka has a parliamentary democratic system of government in which sovereignty of the people and legislative powers are vested in parliament. Executive authority is exercised by a Cabinet of Ministers, presided over by an Executive President. The President and members of the Parliament are elected directly by the people. This study took place during the run-up to an election in April 2004.

Providing health care services in the public sector is the responsibility of the central Ministry of Health (MoH) and eight provincial ministries of health in the provincial councils. The 13th Constitutional Amendment of 1987 decentralised a number of sectors, including health, to the provincial and lower levels with the aim of bringing health services closer to the community. The central MoH is responsible for managing national facilities and teaching hospitals, procuring drugs and supplies, while the provincial MoHs are responsible for managing provincial/district health facilities. Recruitment onto training schemes is undertaken by the central Ministry, which also has responsibility for managing all medical officers. Other categories of staff are managed by the centre or the Province, according to where they are employed. Transfer of staff between the centre and the provinces is possible.

Central Government financial allocations to provincial councils largely cover preventive and curative primary and secondary level health care. These financial allocations so far are not based on objective and transparent measures of population need – only around 6% of funding is via 'criteria-based' grants (weighted favourably towards the poorer provinces).

The health system

Western, Ayurvedic, Unani, Siddha and homoeopathic systems of medicine are practised in Sri Lanka. The public sector comprises Western and Ayurvedic systems, while the private sector consists of practitioners in all types of medicine.

The fastest growing segment of private sector health care is out-patient or ambulatory care, largely concentrated in urban and suburban areas. Over 36 million out-patient visits to private practitioners were estimated to have taken place in 1997, an increase of two million over the 1990 estimate. Of the total ambulatory care market, 46% is serviced by the private sector.

The public sector provides free access to the entire range of preventive, curative and rehabilitative health care for nearly 70% of the population. Almost all inpatient care (95%) is provided by the public sector through a very busy and overcrowded system of national, provincial, general and base (large town) hospitals and a widely spread network of district hospitals and health care units operating at lower levels of utilization and occupancy. Sri Lanka provided around 0.2 inpatient admissions per capita in 1997.

Primary health care is provided throughout the health service and especially in the network of central dispensaries and maternity homes, rural hospitals, peripheral units and district hospitals. Public health services, including health promotion and preventive care, are provided by health units and include services in maternal and child health, family planning and the control of communicable diseases. In addition there is a high level of self-care and utilisation of private pharmacies.

Table 2. Number of health institutions and hospital beds, 1975–2001

Item	1975	1980	1985	1990[1]	1995[2]	2000	2001
Hospitals[3]	458	480	490	422	467	558	569
Patient beds[3]	40,761	43,389	44,861	42,079	47,665	57,027	57,946
Patient beds/1000 pop	3.0	2.9	2.8	2.9	2.9	2.9	3.1
Central dispensaries	355	347	338	278	320	404	406
MOH areas	102	105	111	110	213	252	265

1 Excludes Northern and Eastern Provinces
2 Excludes Jaffna, Kilinochchi, Mullaitivu and Ampara districts
3 Includes maternity homes and central dispensaries
Source: Medical Statistics Unit

Human resources for health

The current major problems are an imbalance in production of different types of healthcare staff, geographic inequity in distribution, and lack of 'fit' between expected job performance and training. Despite steady increases in the numbers of health care workers, there are severe staff shortages in some occupations, particularly specialist doctors, medical teachers, nursing and para-medical tutors, nurses and paramedics. There are also major shortages in some regions, particularly in remote rural areas and in the conflict-affected areas of the country.

At the same time, the government may find it difficult to absorb into the state sector all medical students graduating up to 2010. If this happens, some doctors may move full time into the private sector or seek employment abroad. Compounding all these issues is the questionable relevance and quality of some of the training programmes. All in all, the government will have to contend with the multiple problems of inappropriate skill mix and geographical maldistribution, plus the challenge of introducing a modern system of management geared to appraising the performance of individuals and institutions against their defined roles.[1]

The health situation in the conflict-affected North and East

A two-decade conflict preceding the peace agreement of 2001 pushed the health sector in the North and East provinces to the brink of collapse. Although the government tried to maintain a normal level of health services in the conflict-affected area, this could not be achieved due to destruction of health facilities and lack of qualified health personnel. The displacement of masses of people has created an additional range of physical and psychosocial problems. In addition to the North East, four borderline districts in the North Central, North Western, and Uva Provinces were also greatly affected by the prolonged conflict. The rebuilding of the health system in all these devastated provinces remains a considerable challenge for the country. While a beginning has been made during the last two years to provide essential health services to the population, there remains a need for more concerted planning and massive resource inputs to develop infrastructure and service provision.

Health indicators in the North and East

As a consequence of the conflict, the availability, accessibility and quality of health care have been severely affected, leading to increased morbidity and mortality. Infant and maternal mortalities have risen. The incidence of communicable diseases such as measles, TB, respiratory tract infections, diarrhoeal diseases, vector borne diseases and infectious hepatitis have all registered an upward trend. The absence of family planning services has led to an increase in fertility, thus adding to the burden of the many already impoverished households.

Health infrastructure and human resources in the North and East

Health infrastructure has suffered heavy damage or destruction, particularly in the North. In a survey conducted in 2002, it was found that out of 400 health institutions, 55 were totally destroyed and 49 were not functioning. Many others are in

1 Report to the National Health Advisory Council, 2003; personal communication – Deputy Director General (Planning), Ministry of Healthcare and Nutrition, 2004.

Table 3. Selected health status indicators in the North East and rest of Sri Lanka (2002)

Indicator			Rest of Sri Lanka	North East
Prevalence of diarrhoea in under-fives		24-hour period	3.0%	3.9%
		2 week period	6.7%	7.9%
Exclusive breast feeding of children 4–9 months			50.8%	46.9%
Underweight 0–5 years	Average		24.9%	46.2%
	Male		29.0%	50.2%
	Female		22.8%	42.3%
Low birth weight			16.7%	25.7%
Home deliveries			4.0%	19.4% (38.4% in Mannar)
Maternal malnutrition			N/A	48%
Total fertility rate			1.9%	2.6%
Immunization coverage (under-five with health card)			80.9%	74.5%

disarray due to the absence of maintenance. Damage extends to the water supply and sanitation systems. The health system suffered from a serious lack of medical supplies, medicines, equipment and other necessities.

The availability of human resources for health in the North and East has been very badly affected, particularly medical officers and nurses, with over 70% vacancies in most places. While the Provincial Ministry of Health is making every effort to remedy this situation, medical officers and consultants are very reluctant to take up vacant positions in the absence of some of the basic facilities and communication. The WHO has placed some urgently needed medical consultants in four hospitals – Mannar, Vavuniya, Kilinochchi and Point Pedro – and a number of additional medical officers have been recruited to difficult stations. The Ministry of Health is also recruiting nurses and midwives who will become available for the region in the next few years. All of these measures will help to improve the situation considerably, but a complete return to normalcy is only a medium-term prospect.

As a consequence of the disruption of the facilities and the lack of personnel, the referral system has broken down, and health information and disease surveillance systems are weak. Establishment of a multi-disease surveillance system as part of a wider programme to improve the health status of the poor and vulnerable populations is a priority for the North East Provincial government, supported by WHO.

Filariasis and Leprosy in the North and East

The Anti Filariasis Campaign (AFC) had no staff in the North and East during the conflict and lacks reliable information on the incidence and prevalence of lymphatic filariasis (LF) there. A mapping exercise is currently underway. The AFC considers it possible that LF may be prevalent among the refugee returnees from India.

The Anti Leprosy Campaign, however, feels that leprosy elimination activities continued "without much interruption" during the unsettled period through the Leprosy PHI for Jaffna and Kilinochchi (Settinayake, 2003). Activities in the North and East are a current priority and a comprehensive plan of action is now being implemented. Further details are given in the course of the report.

Funding for the health system

Sri Lanka has achieved extremely good health outcomes given the level of spending on health. Total expenditure on health in 1999 was 39,177 million rupees (then US$ 549 million), of which 13% was capital investment. This amounted to about 3.53% of GDP or 2,068 rupees (then US$ 29) per capita. There is heavy reliance on taxation and out-of-pocket expenditure (approximately 50%) as financing sources.

Since 1990, total health expenditure has been between 3.0–3.5% of GDP, of which the Government's share was around 1.4–1.5%. However, in the last four years, only 1.1 to 1.2% of GDP has been spent on health by the Ministry of Health.

The level of external development assistance to this sector is low compared with other developing countries.

State expenditure has over recent years become increasingly centralized with a large, and increasing, share of state funds being channelled through the Ministry of Health. Though spending on health by provincial councils increased by over 20% in real terms, their share of total state health spending declined during the 1990s.

Drugs policy, procurement and management

Drugs policy

There is no explicitly documented drugs policy at the moment, and the Ministry of Health is now making plans to draft a comprehensive policy that will be adopted in the coming months. However, there are a number of policy statements made by successive governments on different aspects of drugs procurement, management and utilization, and the Ministry of Health issues occasional circulars on managerial issues. The drugs budget is on average about 25-30% of the total health budget every year. For instance in 2002, the total Government health budget was 31 billion rupees (US$ 320 million at current exchange rates), of which 9.5 billion rupees (US$ 98 million) was for drugs (Ministry of Health estimates). It has not been possible to obtain an accurate figure for expenditure on drugs in the private sector, but estimates indicate that it is more than 50% of that in the public sector.

Drugs regulation

The regulation of drugs in Sri Lanka is carried out according to the regulations framed under the Cosmetic Devices and Drugs Act. Under this Act, the Director General of Health Services functions as the Head of the Drugs Regulation Authority (DRA), and is supported by a team of officials in the Ministry of Health and a Drug Evaluation Committee composed of technical experts. The functions of the DRA include the registration of drugs, licensing of retail and wholesale pharmacies, licensing of manufacturers, and issuance of licences to import and transport drugs and to import drugs for personal use. Its work is hampered by lack of technically qualified personnel and other staff, transport facilities, organizational structure and proper methods of evaluation.[1] A National Drug Quality Assurance Laboratory provides technical support for quality assurance.

Drugs procurement

The State Pharmaceuticals Corporation (SPC) is the sole importer of medicinal drugs for the state sector, and also imports a significant proportion of drugs for the private sector. Pharmaceuticals are purchased on a system of worldwide tenders, restricted quotations or monopoly quotations. Drugs imported for the state sector are distributed through the government's Medical Supplies Division whereas those imported for the private sector are sold at SPC retail outlets (Raajya Osu Salas), Franchise Osu Salas and other private pharmacies.

Drugs management

The Medical Supplies Division (MSD) is responsible for consolidating the annual state drug estimates, monitoring overall consumption, and providing the main drug store and distribution for the Ministry of Health. In addition, drugs are stored at Regional MSD depots and hospitals. Storage space is inadequate at all levels of the system, and in hospitals storage conditions are often unsatisfactory. Donated supplies of multi-drug therapy (MDT) for leprosy and albendazole for the lymphatic filariasis mass drug administration are received, stored and distributed by MSD and the regional MSDs.

Sources for the above information include:

The Strategic Framework for Health Development, Ministry of Health, Nutrition and Welfare, Colombo, 2002

National Health Bulletin 2001, Ministry of Health, Colombo

Poverty Reduction Strategy Paper 2001, Government of Sri Lanka, Colombo, 2001

WHO Country Cooperation Strategy Sri Lanka 2002–2005, World Health Organisation, Sri Lanka, 2002.

[1] Background Document for the Project on Health .

3. Drug access PPPs for leprosy and lymphatic filariasis

Scope of the study

Sri Lanka benefits from public-private partner ships for improving access to pharmaceuticals in relation to two tropical diseases: leprosy and lymphatic filariasis (LF). Both are donation programmes, rather than discounted price schemes. Both support WHO disease elimination programmes, with some presumption of a time limit for at least the most intensive activities.

Since 1999, Novartis has donated free multi-drug therapy (MDT) for leprosy for all endemic countries under an agreement with WHO through a programme managed on their behalf by the Novartis Foundation for Sustainable Development (NFSD). The current agreement is due to end in 2005, the WHO target date for elimination, but Novartis/NFSD is to extend its donation until 2010. Novartis does not make MDT commercially available; it supplies WHO with sufficient stocks for all patients in the world. In the case of Sri Lanka, NFSD made a donation of MDT direct to the government from 1988, over a decade before the global agreement. GlaxoSmithKline (GSK) has committed to provide as much free albendazole as is required to eliminate lymphatic filariasis without fixed timing.

In each case, the drug donation programmes established by the pharmaceutical companies are currently operating within a wider disease-focused global partnership – the Global Alliance to Eliminate Leprosy (GAEL) and the Global Alliance to Eliminate Lymphatic Filariasis (GAELF) – and alongside WHO's own elimination programmes. And again in each case, the Ministry of Health in Sri Lanka has had a long-established national campaign. The key objective of this country level study has therefore been to assess the health and health systems impact of the two global drug access PPPs acting in partnership with the national programmes for the elimination of leprosy and lymphatic filariasis.

Background information on the leprosy and LF PPPs/programmes

Table 4 below summarises key information about the global PPPs.

Table 5 summarises the programme objectives and current performance of the national partnership programmes. More detailed information on the Sri Lankan government's Anti Leprosy Campaign and Anti Filariasis Campaign is given in Annexes 3 and 4 respectively.

Table 4. Global Leprosy and Lymphatic Filariasis PPP programmes

	Leprosy	Lymphatic Filariasis
Global PPP programme and objective	*Global Alliance for the Elimination of Leprosy (GAEL)* Elimination by 2005 By "ensuring that all patients, wherever they may be, will have free and equal access to the most modern treatment available".	*Global Alliance to Eliminate Lymphatic Filariasis (GAELF)* Elimination as a public health problem by 2020.
Drug donation	Novartis: commitment to supply free MDT for all endemic countries until the end of 2005 is to be extended until 2010.	GlaxoSmithKline (GSK): commitment to supply as much free albendazole as is required.
Conditionalities	Nothing unreasonable. Novartis requirement that drugs are provided free to patients.	Nothing unreasonable. Mandatory reporting of serious adverse experiences to WHO and GSK.

Table 5. National Leprosy and Filariasis PPP programmes

Sri Lanka	Leprosy	Lymphatic Filariasis
National programme objective	To reduce leprosy and its related distress by reducing the reservoir of leprosy sustainable and by improving the quality of life of people affected by leprosy. To reach the elimination target (<1 patient for 10,000 inhabitants) at subnational level in endemic areas.	To eliminate LF as a public health problem by 2010 through • Interruption of transmission • Prevention of disability • Vector control.
National programme initiated	Longstanding leprosy control activities. Anti Leprosy Campaign (ALC) established in 1954. MDT introduced in 1982 with support from Emmaus. NFSD donation of MDT from 1988, Novartis donation via WHO from 1999.	Anti Filariasis Campaign (AFC) established in 1947. 1999: MDA using DEC 2000: MDA using DEC 2001: MDA using DEC in seven districts, DEC+albendazole in one pilot district 2002 on: MDA using DEC+albendazole in all endemic districts
Population at risk	3.5 million population, resident mainly in districts of the Western, Southern, and North East provinces.	9.8 million (50% of population) in Southern, Western and North-western provinces.
National partners	MoH, provincial ministries of health, Department of Traditional Medicine, Novartis Foundation, WHO at country and Geneva levels, Universities.	MoH, provincial ministries of health, WHO at country and Geneva levels, GSK, NGOs and local sponsors.
Current national/provincial budget contribution	Unquantified. Includes funding for ALC staff, two leprosy hospitals, plus a share of general health services costs including Leprosy Public Health Inspectors and Medical Supplies Division.	Unquantified. Includes funding for AFC staff and laboratories, supply of DEC tablets, payments for health workers, vehicles, plus a share of general health services costs including Public Health Inspectors and Medical Supplies Division.
Current national coverage	100% coverage with MDT achieved in 1983 and sustained to-date. Priority campaign underway in conflict-affected areas.	Coverage above the required 80% in all eight endemic districts of three provinces, except in a few urban areas. Observed coverage of 88.4% in 2003 Mass Drug Administration (independent evaluation). Mapping underway in conflict-affected areas.
Performance against targets	Elimination at the national level achieved in 1995 (five years ahead of the earlier WHO target of 2000). 2003 national prevalence rate of 0.68 against a WHO elimination target of <1 per 10,000 inhabitants. However, 6 districts have rates of 1.1 or 1.2.	Elimination at the national level achieved in 2003. National 2003 microfilaria rate of 0.09%, (a reduction from 0.15% in 2002 and 0.21% in 2001) against a WHO standard for elimination of 0.1%. However, in some small areas, 2003 rate still exceeded 0.2%.
Sustainability	Current GOSL/NFSD agreement is due to end in 2004, but NFSD intends to fund a 2–3 year exit strategy to ensure a sustainable programme. Recent integration of leprosy into general health services will boost sustainability.	GAELF agreement to provide financial support for related activities for five years (to 2006 for Colombo district, and 2007 for all other endemic areas). The programme will be sustainable nationally beyond that date.

The GSK donation is confined to supplies of albendazole. It does not contribute to operational support, which Sri Lanka receives from GAELF. By contrast, since 1988, the Novartis Foundation has provided an extensive range of wider financial and technical support costed at about US$ 1.7 million, in addition to the donation of MDT. This has included support for Anti Leprosy Campaign project staff, a sustained social marketing approach to leprosy, disability care, and monitoring and integration of leprosy services into the general health services.

KEY FINDINGS

There have been no external evaluations of the programmes.

Country priorities, ownership and governance

Government priorities and policy on donations

One concern that has been expressed about drug donation programmes of this kind is whether they have the potential to distort government priorities in the selection of the programmes and the allocation of human and financial resources to implement them.

Interviewees during this study were emphatic that this is not an issue in Sri Lanka. The Director General said that as a matter of general policy, the government would not accept a donation of any kind without being clear that it related to government priorities and that the government was likely to be able to sustain it.

Longstanding government campaigns against leprosy and LF

Both leprosy and lymphatic filariasis have been serious health problems in those areas of Sri Lanka in which they are endemic, and the government is committed to their elimination. Interviewees consistently expressed the clear view that the leprosy and lymphatic filariasis donations were fully in line with longstanding government priorities.

This is evidenced by the fact that the government's Anti Leprosy Campaign (ALC) was established in 1954 as a vertical governmental campaign to plan, coordinate and evaluate leprosy control activities in the country. Indeed Sri Lanka's history of leprosy control dates back to Dutch colonial times when a leprosy asylum – probably the first of its kind in the East – was opened in 1708. As well as the leprosy institutions, since 1970 each district has had one specially trained full-time paramedical leprosy worker, the Public Health Inspector (PHI). Until very recently when leprosy control was integrated into the General Health Service, these 25 PHIs have been involved in conducting clinics for diagnosis and treatment, village surveys, contact surveys, default retrieval and educational programmes under the guidance of three medical officers at the central level of the Anti Leprosy Campaign. There has therefore been a longstanding emphasis on leprosy control in Sri Lanka, with substantial investment of financial, physical and human resources (see Annex 3 for greater detail).

Similarly the Anti Filariasis Campaign (AFC) was established in the Ministry of Health as long ago as 1947 (see Annex 4). Filariasis control activities were decentralised in 1989. The responsibilities of the Provincial health authorities cover planning, implementing and monitoring filariasis control within the framework of the national programme. Currently the AFC directorate at the centre has a staff of 35, including four medical officers, and two laboratories. At provincial level there are five dedicated medical officers to cover the eight endemic districts, plus public health inspectors.

As a further indication of ownership and commitment, Sri Lanka participates actively in the Global Alliance for the Elimination of Lymphatic Filariasis (GAELF) established in May 2000. Both the Director General of Health Services and the Director of the Anti Filariasis Campaign will be attending the Alliance's global meeting later this month (March 2004). Sri Lanka has not been invited to meetings of the Global Alliance for the Elimination of Leprosy since it achieved elimination at national level in 1995 before the establishment of GAEL. This seems a missed opportunity to share lessons from Sri Lanka's record of success and innovation, particularly in relation to social mobilisation.

Marginal resource costs arising from the donation programmes being studied

In both cases, the country's approach to the use of drugs in control pre-dated the donation programmes by the Novartis Foundation for Sustainable Development (NFSD) in the case of MDT for leprosy and GlaxoSmithKline (GSK) in the case of albendazole for LF.

In 1982, Sri Lanka was the first country in Asia to introduce MDT as the standard treatment for all registered leprosy patients, with financial and material help from the Leprosy Relief Work Emmaus, Switzerland (Emmaus). NFSD became involved in 1988 when it joined with Emmaus to provide technical, financial and material support to the ALC, including MDT for all leprosy patients in Sri Lanka. The original NFSD drug donation therefore substituted for supplies already being supported by another body and did not itself have resource consequences. For more than a decade NFSD supplied the MDT directly to the Ministry of Health but,

since Novartis' 1999 agreement with WHO to donate MDT to all endemic countries, supplies for Sri Lanka have been routed via WHO. The new arrangements were necessitated by the shift to a global programme and seem to be working without difficulty.

For LF, from 1999 Sri Lanka had already been conducting a single dose mass drug administration (MDA) of diethylcarbamazine (DEC) alone for the eight districts comprising the entire endemic area. After a 2001 pilot in the Colombo district using a combination of albendazole and DEC in single doses, the approach since 2002 has been for a free annual MDA of the entire endemic area using the combination. The State Pharmaceutical Manufacturing Corporation supplies the government-funded DEC tablets, and the albendazole comes from the GSK donation via WHO. While the donation of albendazole has been seen in Sri Lanka as vital to the introduction of a more effective drug regimen, additional resource costs (human and financial) have been only marginal since annual mass drug administrations were already conducted.

Funding of the programmes

There is demonstrably strong long-standing national commitment to these tropical disease programmes, backed by government dedication of unquantified, but significant, resources given the resource constraints (both financial and human) currently facing the country.

National and provincial funding for the leprosy programme is unquantified but includes as a minimum the cost of ALC staff, two leprosy hospitals, plus a share of general health services costs including PHIs and Medicines Supply Division.

This state contribution is augmented by sizeable donations from the Novartis Foundation for Sustainable Development and Emmaus. Under the agreement in place until end 2004, Emmaus and NFSD provide base funding for ALC project activities amounting in 2004 to 2.5 million rupees each (US$ 25,770 at current exchange rates) – a total of 5 million rupees (US$ 51,540). This covers three project staff plus two drivers and vehicles. In addition NFSD has funded, and continues to fund, the range of specific activities outlined earlier. The Foundation estimates that, excluding unquantified drug costs, from 1988–2003 it has provided funding support of about US$ 1.7 million for ALC base costs (shared 50 : 50 with Emmaus) and for activities which NFSD supports entirely, including advertising, training, print materials, etc.

National and provincial funding for the LF programme is similarly unquantified but includes the cost of 35 AFC staff and laboratories, plus a share of general health services costs including five medical officers, PHIs and Medical Supplies Division. For the annual mass drug administration exercises, the government provides funding for the supply of DEC tablets, payments for health workers and vehicles.

The cost of GSK's donated supplies of albendazole to Sri Lanka is unquantified. In 2003, 9.3 million tablets were provided, and the same amount has been requisitioned for 2004. The market price in Sri Lanka for albendazole is 80 rupees (US$ 0.87) per tablet, though the actual cost to GSK would clearly be lower. The government also benefits from some external support in addition to free drugs. For the 2002 MDA, Sri Lanka received US$ 67,096 for social mobilisation activities (US$ 47,096 from WHO Geneva and $20,000 from the LF Centre at the Liverpool School of Tropical Medicine). WHO Geneva provided consultancy advice on the LF social mobilisation plan.

Neither programme receives direct support from any bilateral or multilateral partner other than WHO, and the AFC from the DFID-funded Lymphatic Filariasis Support Centre of the Liverpool School of Tropical Medicine.

Governance

The Anti-leprosy and Anti Filariasis Campaigns are located within the Department of Health Services, under the Deputy Director General for Public Health Services (see Annex 5 for organigram). Given the decentralisation of health services in Sri Lanka, the central campaign units are responsible for preparing and implementing the respective national plans, monitoring and evaluating the situation country-wide and providing technical guidance to the provincial control programmes. The provincial health authorities are responsible for planning, implementing and monitoring control within the framework of the national programme. The points made in preceding paragraphs demonstrate the active national ownership of the programmes.

The study found strikingly contrasting pictures of the degree of involvement in national programming by the drug donors concerned.

In relation to lymphatic filariasis, GSK has no involvement or influence at country level beyond the crucial step of providing free drugs through WHO. The prime interface for Sri Lanka's Department of Health Services is with WHO Geneva for the WHO elimination programme and as the secretariat for the Global Alliance. There is no WHO regional involvement. The Director of the Anti Filariasis Campaign has no contact with GSK beyond emailing them a copy of her annual reapplication and report. There is a local GSK medical adviser but he has no role in the donation programme. His only involvement has been that, like several other local businesses and hospitals, he sponsored banners for the MDA.

By contrast, the Novartis Foundation for Sustainable Development – and in particular the head of its Health Care Sector – has played a very active and personal role in developing a wide-ranging programme of technical and financial support to the Anti Leprosy Campaign that goes far beyond the simple donation of drugs. The head has participated in ALC planning meetings on a regular basis and is felt to have been influential, though decision-making is seen as unequivocally a matter for the Department of Health Services. NFSD follows WHO advice on technical issues.

Both government and NFSD appear to regard this as an excellent and effective partnership, and attest to mutual trust and respect. From the Department's point of view, initial suspicions about NFSD's motivation were rapidly dispelled. NFSD has supported them over a lengthy period in making a reality of some innovative approaches to leprosy care and control, (most notably a tremendously successful social marketing campaign to change the image of leprosy), and in the challenges of integrating leprosy services into the General Health Services. The broader partnership stimulated by NFSD has embraced a wide range of staff at provincial and regional level as well as centrally. From NFSD's point of view, they have found the Sri Lankan health services at all levels effective, cohesive, and politically committed to the Anti Leprosy Campaign but free of political games-playing. Sri Lanka has been the test bed for approaches which NFSD has then disseminated to other countries, e.g., the social marketing approach has been adapted for use in Brazil, Mexico and Madagascar.

Both the ALC and the AFC hold their own accounts. Cheques on the ALC account have to be signed by the Director and countersigned by a nominee of the Novartis Foundation. This is an acceptable control mechanism, and there has been no instance where the nominee has refused to countersign. Joint quarterly audit reports on the Emmaus and NFSD funds are undertaken by independent accountants and provided to the Ministry of Health as well as the donors.

Both donations comply in full with the Interagency Guidelines for Drug Donations (details in Annex 7).

The study found no evidence or allegation of unreasonable conditionalities attached to either drug donation. The only – entirely reasonable – conditionality laid down by GSK is to report to them and WHO any severe adverse reactions encountered during treatment. Novartis requires that the donated MDT be given free to patients. These drugs have little or no commercial value and therefore do not raise issues of leakage and security conditions. Reporting requirements are regarded as detailed but manageable and acceptable. The MOU between the Government of Sri Lanka and NFSD provides for the programme to be evaluated on an annual basis.

In relation to WHO's current role in handling reapplications for MDT, the study was told of one or two instances where WHO sought clarification of the amounts being requested (e.g. in relation to child packs) but these were resolved without difficulty.

Publicity about the donations seems to have been extremely limited in Sri Lanka. Generally the study found that few people apart from those directly involved were aware that the drugs were being donated by NFSD and GSK, or of the considerable extent of NFSD's wider support. The NFSD logo has been added to the MDT registers and forms only this year (2004).

Integration with general health services

Both the leprosy and the LF programmes are now fully integrated with general health services.

Integration of the historically disease-specific 'vertical' leprosy programme is a recent venture, launched in 2001 as a solution to operational and cost-effectiveness problems caused by the campaign's success in reducing prevalence rates. PHIs were travelling long distances to hold field clinics with few or even no patients. Moreover, a consequence of the existence of a specialist Anti Leprosy

Campaign was that the country's curative health facilities did not consider leprosy to be their responsibility.

Under the integrated system, a patient can turn to any curative health facility or dermatological clinic in the country, or to the ALC's Central Leprosy Clinic, and receive MDT. Monthly follow-up doses of MDT can be obtained directly from the pharmacist on presenting the patient MDT card if the patient does not wish to see a doctor. Private practitioners can obtain MDT free of charge directly from the Central Leprosy Clinic. Complications that cannot be managed by the health facility are referred to the closest dermatological clinic or the Central Leprosy Clinic.

Only 20% of health institutions (mainly major hospitals) reported new leprosy cases in the first two years after integration. Nonetheless, with strong encouragement from WHO, at least small stocks of MDT are maintained at all health units in line with the policy to increase the accessibility of MDT, especially in low endemic situations. This is seen as the right policy, though having stocks in so many places poses logistical problems in relation to expiry dates.

The scope for individual patients to access care and drugs in several places creates the potential for recycling and over-reporting which the ALC attempts to track through its computerised data base. There may also be the possibility under integration of some over-diagnosis, due to less experienced health staff also being involved in diagnosis and surveillance, with the result that a few non-leprosy patients may receive leprosy treatment.

The actual process of integration posed some major planning, operational and change management challenges and was supported by the Novartis Foundation. It entailed amongst other things reorienting and motivating large numbers of doctors and other staff in some 1,000 health institutions, producing a special leaflet for Ayurvedic practitioners on leprosy recognition and referral, and a formidable logistical operation to supply all health facilities with MDTs and other supplies such as specially-designed patient forms and registers, patient information and posters. A professional advertising campaign was used to create awareness of the availability of treatment at all health facilities as well as overcome residual stigma attached to leprosy. A special campaign was developed for the Tamil community in Sri Lanka, and a 'think leprosy' campaign targeted health care providers.

Regional epidemiologists were identified as the 'managers' of the integration process together with the leprosy PHI for each district.

Despite the challenges, the general view seems to be that integration is working, in the sense that expertise has been developed at district level; effective networks have been created; and patients have more choice and easier access.

The distribution of MDT continued to be handled centrally by the ALC until 2004 when responsibility passed to Medical Supplies Division (MSD). The four types of MDT – paucibacillary (PB) adult, PB child, multibacillary (MB) adult and MB child – are now line items in the Annual Drug Estimate books issued to all health institutions, providing MSD with estimates of drug requirements.

Fuller details are given in Annex 3.

One study term of reference concerns the PPP's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs. In real terms only the NFSD operates on the ground in Sri Lanka, and both LF and leprosy drug donations feed into pre-existing government programmes which are now in the same Ministry of Health department centrally. There is therefore neither scope nor need for a PPP coordination mechanism at country level, but the NFSD has tried to support the Anti Leprosy Campaign in disseminating lessons learned, especially to the TB team which faces similar challenges.

Health and health systems impact

Health impact

Health impact on leprosy is likely to relate not only to the use of donated MDT but also to a range of other activities, several funded or supported by NFSD including social marketing activities and the integration of leprosy services into general health services.

On the WHO definition of elimination as less than one patient for 10,000 inhabitants, elimination of leprosy at a national level was achieved in Sri Lanka in 1995, five years ahead of the WHO's target date. Sri Lanka was only the second country in Asia to achieve national elimination.

The challenge now is to secure elimination at subnational level. In 2002 the overall national prevalence rate was 0.8 per 10,000 inhabitants. However, five districts still had rates of 1–2 per 10,000, and two districts in conflict-affected areas

had rates greater than 2.0. The highest rate of 3.0 was found in Batticaloa in the conflict-affected Eastern Province. New figures for 2003 show that the national prevalence rate had dropped to 0.68 patients per 10,000 and one further district had achieved elimination. No district, including Batticaloa, had a rate above 1.2 per 10,000 inhabitants. The ALC is now focusing attention below district level to reduce rates in remote areas.

For LF, national mass drug administration of albendazole with diethylcarbamazine (DEC) began in 2002 so to-date there have been only two rounds. It is too early to demonstrate the impact of the drug donation, given the long potential life cycle of the filiaria worms. The recent marked downward trend in LF cases is encouraging but began before the use of albendazole. In 2003, elimination of LF as a public health problem was achieved at national level with a microfilaria rate of 0.09%. This marks a reduction from 0.15% in 2002 and 0.21% in 2001. However, in some small areas, the rate in 2003 still exceeded 0.2%.

Measurement of coverage by socio-economic status, age and gender

As in the Uganda pilot study, there are no routine socio-economic data on leprosy and LF patients. Given the high levels of coverage, it is assumed that the drug donations benefit the poor particularly, because the MDT is provided free in unlimited amounts and LF is primarily a disease of poverty. Assessments undertaken by the leprosy programme itself, with the support of University-based programme consultancy, have confirmed that all groups, including poor people and those living in remote and rural areas, are receiving MDT drugs as planned.

The LF mass drug administration (MDA) of DEC and albendazole is targeted on the total population in the endemic areas, excluding only children under two, pregnant and lactating women, and the very sick. Grass roots level health workers are in constant touch with the poor and the remote, and working from lists of householders, seek to ensure participation in these programmes.

There are no major issues arising from the public/private split in provision, since the leprosy MDT is available to private practitioners free of charge, for free provision to their patients, and the LF MDA covers the whole population in the target areas.

The child rate is a key indicator for leprosy and is closely monitored. New cases among children under 15 as a percentage of total newly-detected cases for the year rose from 10.07% in 2002 to 11.48% in 2003, though the actual number of cases remained broadly the same (223 and 221 respectively).

The Gampaha district visited by the study team covers 10% of Sri Lanka's total population. The MOH area with the highest leprosy rates in the district (and the second highest population density) is Negombo, a coastal town including a low-income, low-education fishing community. As demonstrated in Table 6 below, there is no sustained marked imbalance between genders among leprosy patients in the district. Over the last three years, there has been a tendency to a slightly higher number of male patients' district-wide and of female patients in Negombo.

Health systems impact

Drug ordering, receipt and distribution

One immediate impact on the health system concerns tasks relating to drug ordering, receipt and distribution. Table 7 below gives summary details of the full cycle.

Annual requirements of Novartis' MDT are shipped in batches with WHO as the consignee. With effect from 2004, the Ministry of Health Medical Supplies Division (MSD) handles clearance, stores the drugs and distributes through its routine systems. There are surprisingly long lead

Table 6. Leprosy cases by gender in Gampaha district and Negombo MOH area

	Gampaha district male	Gampaha district female	Negombo MOH area male	Negombo MOH area female
2001	215 (59%)	149 (41%)	53 (50%)	53 (50%)
2002	152 (50%)	150 (50%)	42 (40%)	63 (60%)
2003	143 (57%)	108 (43%)	39 (49%)	41 (51%)

Source: J. Perera District Leprosy Control Officer (PHI), Evolution of the Elimination of Leprosy Gampaha District after Integration, 2001–2003

Table 7. Current cycle of drug ordering, receipt and distribution

Sri Lanka	Leprosy	Lymphatic Filariasis
Application/reapplication process and orders for drugs	By Director, Anti Leprosy Campaign/ Director General of Health Services to WHO HQ. Annual reapplication.	By Director, Anti Filariasis Campaign/ Director General of Health Services through WR to WHO HQ. Annual reapplication.
Estimation of drug requirements	i) Formerly by Director, Anti Leprosy Campaign with district health teams. From 2004 on, MSD with support from ALC. ii) WHO supplies to a formula based on endemicity of area, attendance at health units minus existing stocks.	By Director, Anti Filariasis Campaign, based on district population estimates minus existing stocks.
Receipt of drug in country	WHO as consignee. Ministry of Health Medical Supplies Division (MSD) collects from airport.	WHO as consignee. Ministry of Health Medical Supplies Division (MSD) collects from airport.
Storage	MSD in Colombo.	MSD in Colombo.
Distribution to district level	MSD delivers quarterly to Regional Medical Supplies Division who in turn distribute to health institutions. MSD delivers direct to 14 Teaching Hospitals. Buffer stocks held in regional stores and by PHIs.	Regional Medical Supplies Division collect the supplies on the basis of a distribution list prepared by ALC from district returns, and deliver to districts, who deliver to MOHs.
Distribution to individuals	Patient collects monthly supply from supervising health unit during monthly visit. (No Accompanied MDT)	House-to-house using 50,000 Filariasis Prevention Assistants; House-to-house and booth distribution in Colombo district.
Links with other programmes	Integrated into general health services from 2001. In most districts the Public Health Inspector formerly dedicated to leprosy now also undertakes other activities such as rabies, TB and malaria control.	Integrated into general health services.

times in the routine national drug ordering system with, for example, health institutions framing their estimates of need in 2004, the drug volumes being ordered in 2005, and the actual drugs received in 2006. It is too early to comment on the impact on the supply chain of the full integration of MDT for leprosy services into the general health services. The study found no evidence hitherto of difficulties in supply or stockouts. Supplies were held in all units visited, including on unannounced visits.

The approach for LF is slightly different since the mode of operations is a mass distribution to inhabitants on a single day. Albendazole is shipped direct by GSK, with WHO as the consignee, normally 2–3 months before the date fixed by the AFC for the mass drug administration (MDA) – usually the last Sunday in July. AFC find this a satisfactory arrangement. However, their own distribution to districts could be improved. Staff in the Gampaha district stated they have on occasion received their supplies from the AFC only one week before the MDA which allows too little time for local distribution and logistics. Ideally they should receive stocks two weeks before the MDA.

Overall, arrangements are broadly satisfactory. The donations themselves are now fully integrated into general systems and impose no unreasonable burden.

Wider impacts on the health system

The GSK albendazole donation has no wider impacts on the health system, either positive or negative. The donation itself does not offer any associated support to operations in Sri Lanka, though funding is received from WHO and the Liverpool School of Tropical Medicine for social marketing and MDA activities. At the same time, the donation imposes minimal additional burdens since an annual mass drug administration of the entire known endemic area (using DEC alone) was already being undertaken.

In relation to leprosy, the Novartis Foundation's donation of MDT did not create additional costs

or burdens since Sri Lanka was already using MDT with support from Emmaus.

However, over the last 15 years, the Foundation has supported a much broader programme with significant beneficial impact on the health system (see also Annex 3). This has included amongst other activities extensive and sustained support for:

- a model social marketing campaign which would not have been affordable without NFSD support
- the integration of leprosy services into the general health services
- the physical and economic rehabilitation of leprosy-affected people, including through training of surgeons, leprosy health inspectors and physiotherapists and teaching patients to care for their own disabilities
- improvements in methods of monitoring and record-keeping, including the development of a computerised database, design of new patient cards and reports
- development and implementation of a plan for leprosy control in the North East.

It was the unanimous view of all relevant interviewees that these activities had made a major and very successful contribution to the leprosy campaign and to the wider health system. There is scope for other programmes to apply some of the lessons learned, particularly in relation to monitoring and record-keeping and to social mobilisation. A TB social mobilisation campaign to be launched in April 2004 with GFATM funding has liaised closely with the ALC. There were no illustrations of deleterious impact on the health system.

Scale and sustainability

Scale

Both the leprosy and the lymphatic filariasis programmes are operating at full scale in affected areas, subject to some residual difficulties in the North East as a result of the unrest. For leprosy, a comprehensive plan of action for the North East is currently being implemented with support from the Novartis Foundation. This includes training and logistical activities, and a social marketing campaign exclusively for the North East which is just about to be launched. Continued support for the North East is a key priority for the Novartis Foundation.

At this moment the AFC does not have reliable information on the incidence and prevalence of LF in the uncleared areas of the North and East. A mapping exercise has just begun and will provide a better picture by the end of 2004. Currently the campaign has a total of 16 patients from the North and East, eight of whom are refugee returnees from India (Tamil Nadu and Kerala).

Sustainability

For both programmes, sustainability for at least some years to come is critical if comprehensive elimination at subnational level is to be secured and maintained.

In relation to leprosy, the current agreement for substantial support from the Novartis Foundation comes to an end this year, as does the Emmaus commitment to provide 2.5 million rupees per year. While no formal agreement for further support has yet been signed, both the ALC and the Novartis Foundation share a concern that the laudable achievements to date and the prospects of success should not be jeopardised by withdrawing support too abruptly. There is common thinking on the need to develop a comprehensive and cohesive exit strategy to be implemented over the next two to three years with NFSD support. Core elements are likely to be continued support for surveillance; deformity care; and the North East where some of the attitudinal changes brought about elsewhere in the country have yet to be secured. A key general challenge will be how to keep leprosy at the forefront of everyone's consciousness for the next four to five years, in the face of low prevalence.

Interviewees made the point that almost as important as the funding was the considerable motivational and profile-raising effect of external involvement and support for the Anti Leprosy Campaign.

For LF, the Global Alliance for the Elimination of Lymphatic Filariasis through the WHO has undertaken to provide financial support for related activities for five years, as well as unlimited supplies of free albendazole. The agreement dates from 2001 in the case of Colombo district, and 2002 for all other endemic areas. The Anti Filariasis Campaign considers that this will be sufficient to meet needs during the period to 2007, and that the programme will be sustainable nationally beyond that date.

Perceived benefits of the drug access PPPs studied

Benefits of the drug donations

- The key benefit of the donation programmes is that they provide a sustained and high quality supply of effective drugs which the government of Sri Lanka would otherwise struggle to afford. The study team was repeatedly told of drug shortages or irregular supplies for other treatments, because of funding problems.
- A particular benefit of the introduction of MDT for leprosy was that it meant patients no longer need be admitted to leprosy hospitals, or take lifelong medication. This benefit was secured with Emmaus support for the introduction of MDT in 1982, and has been sustained by NFSD/Novartis since 1988.
- Drug presentation is felt to be very important. The current Novartis MDT blister packs are seen as attractive and user friendly. There is a widely held view that they enhance compliance through their design and through creating confidence in the patient so that they go on taking the drugs (unlike some loose drugs apparently which are misguidedly thrown away after a few days as inferior). Blister packs eliminate shortages or expiry occurring in an individual drug which could lead to a patient developing resistance to the other drugs.
- Novartis' responsiveness to problems was appreciated. There had earlier been difficulties with clofazamine instability because of climatic conditions so Novartis invested significantly in new more resilient blister packaging. Another example was that dermatologists occasionally need additional supplies of clofazamine to treat severe ENL reactions, and had been cutting up the blister packs with consequent wastage of other drugs. Under an additional agreement with WHO, Novartis are now donating clofazamine alone for this purpose.
- Similarly albendazole for lymphatic filariasis is seen in Sri Lanka as a good drug for the purpose: it is felt to be very effective, has a user-friendly one dose regimen, and is pleasant to take with a peach smell so that children will chew it.
- There is an ancillary benefit of mass administration of albendazole in its action as an anti-helminthic. Local GSK private sales of albendazole for anti-helminthic purposes fell by 50% in 2003, following the first full MDA including albendazole in 2002. Other suppliers of anti-helminthics saw sales fall by 10–30%.

Benefits of the wider NFSD support for the Anti Leprosy Campaign

- The extensive programme of wider support from NFSD over a fifteen-year period has made a major contribution in Sri Lanka to progress in eliminating leprosy, and reducing the stigma of leprosy. Its most notable achievements have been support for an innovative and extremely successful social marketing campaign, and for the challenging process of integrating leprosy services into the general health services. At the same time its sustained support for more routine activities over a long period should not be underestimated.
- Interviewees reported that initial governmental misgivings about the involvement of a Foundation related to a major pharmaceutical company were rapidly dispelled by working with the NFSD. In practice the benefit of this external stimulus in anti-leprosy activities in Sri Lanka is felt to have been considerable. There is general consensus amongst interviewees that NFSD's work with the ALC has helped raised awareness, played an instrumental part in bringing various key groups together and winning their confidence, and contributed to a more focused and innovative consideration of leprosy control. NFSD's support for integration appears to have helped secure acceptance of what appeared a difficult transition, particularly for those PHIs who had such a personal stake in the elimination campaign.
- The NFSD's pre-integration practical support for leprosy PHIs both motivated and facilitated their active engagement in the elimination programme, in which they have played a crucial part. Support included allowances to recognise their extra responsibilities for diagnosis and treatment, means of transport, funds to call regional people to meetings etc.
- The study team was told that the NFSD approach had helped develop a better understanding of management techniques among Sri Lankan partners working within a relatively bureaucratic government system.

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Outstanding challenges of the drug access PPPs studied

General issues relating to elimination programmes

- The main challenge relates not to the drug access PPPs themselves but to all successful elimination programmes as they reach the endgame. One challenge of success is how to keep the disease at the forefront of people's attention when the numbers of cases become very low. The Anti Leprosy Campaign is now facing that challenge.
- There is also an organisational challenge. The drive and commitment needed to secure elimination is confronted by the reality that some at least of the individuals concerned are working themselves out of a job. In Sri Lanka there is a lack of successors to leadership positions as leprosy doctors retire. This problem has been compounded by some uncertainty over the PHIs' position post-integration. As individuals, these highly trained paramedicals have lost clinical responsibilities and therefore their allowances. They are assuming responsibilities for other disease activities and there is an issue about how long a specific leprosy focus will still be needed. The ALC's view is that it is premature to scrap specialist leprosy PHIs completely and that the position should be reviewed in three years time.

Specific issues relating to the drug access PPPs in Sri Lanka

- In relation to LF, the Anti Filariasis Campaign judges that all that is required is delivery of existing commitments to free albendazole from GSK and financial support from WHO and partners up to 2007, and that the programme will be sustainable nationally beyond that date, including in the North East where incidence and prevalence have been low.
- The position in relation to the Anti Leprosy Campaign is somewhat more complicated. The continued supply of free MDT from Novartis is a prerequisite. Beyond that, the study team was told that, if wider NFSD support were withdrawn in 2004, the number of leprosy cases would be unlikely to go up. However, there is common agreement between the ALC and NFSD about the desirability of a gentler transition to safeguard current achievements, secure the elimination target at subnational level with particular emphasis on the North East, ensure the surveillance system works effectively under integration, and retain interest among key players, especially doctors. The study team welcomes the NFSD's commitment to developing an exit strategy for two to three years beyond 2004.
- There do not appear to be any organisational problems involving the drug access PPPs to be resolved.

4. Assessment of potential benefit from other drug access PPPs

The study's Terms of Reference require an assessment of whether Sri Lanka is benefiting from all the drug access PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

The range of drug access PPPs identified in this series of studies covers leprosy, lymphatic filariasis, malaria, onchocerciasis, sleeping sickness, trachoma and HIV/AIDS (including some for opportunistic infections).

Drug access PPPs for tropical diseases

As outlined above, Sri Lanka is already benefiting from drug access PPPs for leprosy and lymphatic filariasis.

For the reasons set out in Table 8 below, the study team has concluded that the country would not be eligible for, or benefit from, the other current drug access PPPs for tropical diseases.

Global Fund to Fight AIDS, Tuberculosis and Malaria support

The Government submitted two proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and received a total of US$ 8.5 million dollars and US$ 6.6 dollars respectively for malaria and for TB for five years. The first tranche of funds has been received and the two programmes are underway.

The malaria proposal aims at intensive malaria control among the hitherto marginalized populations in conflict-affected districts in Sri Lanka, who are presently afflicted with a high malaria burden. It plans to strengthen the present programme that is being carried out by the government in partnership with UN Agencies and NGOs, so that it can accommodate the large groups of displaced and marginalized people who are now re-entering the mainstream. The key strategies are to conduct outreach clinics to detect and treat malaria patients, to confirm diagnoses using Rapid Diagnostic Kits and to detect asymptomatic parasite carriers among school children. The funds needed for malaria drugs are included in the proposal and the anti-malaria campaign is not planning to solicit any donation of drugs during the project period.

The GFATM support for tuberculosis aims to improve TB control by enhancing the efficiency of the DOTS programme through increased outreach activities in underserved areas and promoting partnerships with NGOs and the private sector. Addi-

Table 8. Assessment of benefit to Sri Lanka of other drug access PPPs

Drug Access PPP disease	Assessment of benefit to Sri Lanka
Malaria	Malaria is a major public health problem in Sri Lanka but the Novartis/WHO agreement on discounted prices for Coartem is not relevant at present because there is no multi-drug resistant malaria and less expensive drugs are currently effective. Careful monitoring of resistance is desirable in case of future need to access Coartem.
Onchocerciasis	Onchocerciasis is not endemic in Sri Lanka.
Lymphatic filariasis co-endemic with onchocerciasis	The Mectizan ® Donation Programme donates free supplies of Mectizan ® (ivermectin) in Africa for use in lymphatic filariasis where it is co-endemic with onchocerciasis. Given the absence of onchocerciasis in Sri Lanka, the appropriate regimen is albendazole plus DEC rather than albendazole plus Mectizan ®.
Sleeping sickness	Sleeping sickness (trypanosomiasis) is not endemic in Sri Lanka.
Trachoma	Trachoma is not endemic in Sri Lanka.

tionally it plans to provide self-employment opportunities to TB patients and will contribute to poverty reduction. Since the start of the DOTS programme, involvement of the NGOs and the private sector has improved case detection and case holding, with an overall impact on compliance.

Under a Memorandum of Understanding between WHO and Novartis, countries receiving some funding for their TB and TB/HIV programmes from the Global Fund and also approved by the Global Stop TB Partnership's Global Drug Facility (GDF) are eligible for the Novartis donation of fixed dose combination TB drugs.[1] The donation is limited to a few countries to ensure that it can cover drug needs over the five-year period and provide additional support, if needed.

Because of the synergies between TB and leprosy, the NFSD has made clear its intention to offer the Sri Lankan Department of Health Services a package of support for social marketing, training etc if the government successfully applies to the GDF.

At the time of the study fieldwork, no application had yet been made to the GDF.[2] The Director of the TB Programme is discussing this with clinicians and other partners on this subject, and is fully aware of the availability of support for anti-TB drugs through the Stop TB Partnership's Global Drug Facility. She also noted that a social marketing programme, similar to that undertaken for leprosy in the early nineties, would have a very beneficial effect in reducing the social stigma still attached to TB in the community. It would also increase compliance with DOTS treatment.

Drug Access PPPs for HIV/AIDS

The HIV/AIDS programme did not receive support from the GFATM, but from the World Bank. The programme has already included anti-retroviral treatment for all HIV-positive mothers, to prevent mother-to-child transmission, and also for any health workers who have been accidentally exposed to the infection. The government has made a policy decision to include anti-retrovirals as a part of the control strategy in the programme starting from July 2004. Currently the programme managers are undertaking the preparatory work in this regard, particularly to monitor patients being treated and to do the regular laboratory assays. The budget needed for the drugs is available from the World Bank grant itself. However, there is a clear opportunity for exploring the place for drug donations/discounts in the coming years.

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[1] All drugs supplied through the GDF have to go through an extensive process of prequalification. Country applications to the GDF are reviewed by a Technical Review Committee.

[2] An application has subsequently been made to the GDF (August 2004).

5. Summary study conclusions

This was a rapid, largely qualitative study of two drug donations PPPs in Sri Lanka. It examined Novartis' donation of multi drug therapy (MDT) for leprosy and GSK's donation of albendazole for lymphatic filariasis (LF), within the wider disease-focused global partnerships – the Global Alliance for the Elimination of Leprosy and the Global Alliance to Eliminate Lymphatic Filariasis – and alongside WHO's own leprosy and LF elimination programmes. The study also examined the substantial support for the Sri Lankan Government's Anti Leprosy Campaign provided by the Novartis Foundation for Sustainable Development (NFSD) since 1988.

Since the NFSD itself donated MDT to Sri Lanka before the more recent global agreement between Novartis and WHO, on occasions there is little distinction made at country level between the Novartis Foundation and the Novartis pharmaceutical company.

A key question for the study is the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitates better drug availability and access by the poor. Further questions include whether the availability of free drugs distorts decisions on priorities or prices, and the feasibility and sustainability of taking such initiatives to scale.

Key conclusions are as follows:

- There was complete unanimity among interviewees in Sri Lanka that the drug donation partnerships have materially assisted the national leprosy and LF elimination programmes. The key benefit is that they provide a sustained and high quality supply of effective drugs that the government of Sri Lanka would otherwise struggle to afford. Given the nature of the diseases and the fact that the drugs are provided to people free, the donations are likely to have assisted access to such drugs by the poor.[1]
- Both elimination programmes were long-standing government campaigns, considerably predating the drug donations. There has been no skewing of priorities or diversion of scarce human and financial resources either at central or provincial levels, as a result of the drug donations.
- Both programmes are running at full scale in all affected districts, subject only to challenges caused by the recent conflict in the North East which are now being addressed intensively. The Anti Leprosy Campaign has a specific plan for the North East.
- The donated drugs have little commercial value and the issue of prices does not arise significantly, though local commercial sales of GSK's albendazole as an anti-helminthic have fallen following the free mass drug administration of albendazole for LF.
- From the country perspective, there appears to be no evident direct commercial benefit for Novartis or GSK from the drug donations, or indeed from the wider support provided by the Novartis Foundation for Sustainable Development. A supporting study at global level suggests that any benefit relates to generalised corporate public relations, better relations with governments and improved staff morale.
- There has been no formal evaluation of NFSD's 15-year support for the Anti Leprosy Campaign, amounting in cash to about US$ 1.7 million excluding the cost of drugs. It is likely to make a good study. The unanimous view among interviewees was summed up by the comment that it "has been a singular success story". NFSD's involvement in Sri Lanka has provided real benefit and is perceived as immensely supportive but

[1] It should be noted that Sri Lanka was being provided with free MDT drugs for leprosy by a Swiss charity, Emmaus, before the original NFSD donation.

not directive. Partnership working appears to have been excellent. National partners perceive no downsides.

- NFSD support has been especially successful because it was not just a vertical drug donation, but part of a much broader programmatic approach. For example, without external support for an extensive social marketing campaign, the Sri Lankan government's Anti Leprosy Campaign is unlikely to have been so successful in flushing out new cases or reducing stigma. The Sri Lankan experience suggests that there is scope, perhaps through Foundations particularly, for the successful application of more commercially-oriented practices such as social marketing.
- Credit for success must also go to national partners. Regular government machinery has not micromanaged the campaigns which have had considerable discretion to make or shape key decisions. External support, both financial and technical, has meant they have not required additional assistance from government. The Anti Leprosy Campaign has benefited from able and committed leadership over time, and from the wider partnership in country (e.g. with universities, and the Department of Traditional Medicine). The Anti Filariasis Campaign is similarly benefiting from effective leadership.
- NFSD financial support was significant but fell short of flooding the system with money which would probably have had a non-sustainable effect on the programme and a deleterious effect on other programmes.
- Successful approaches in the Anti Leprosy Campaign provide lessons for other parts of the Sri Lankan health service particularly in terms of social marketing and of approaches to record-keeping and analysis, including software development. Lessons about stigma, compliance and expecting working people to come for medication in their own area are particularly relevant to the TB programme which is seeking to build on the leprosy experience.
- The NFSD-supported integration of leprosy services into general health services has so far been a positive experience in Sri Lanka, despite the inevitable operational and human change management challenges. Anecdotally it is providing a more accessible service for patients. Even before integration, because of issues around stigma, the ALC strategy was based on trying to motivate people to come for treatment rather than case finding and pursuit.
- Diseases that can be 'eliminated' as major public health problems are good choices for health commodity-focused PPP support because of their time-limited nature, thus minimising the risk of creating a dependency relationship and unsustainable programmes. In the case of NFSD's support for leprosy elimination over and above Novartis' continued supply of MDT, there is a need for a realistic exit strategy that will meet the expectations of the people concerned and the requirements of the programme. Both partners regard the prospects of a smooth exit and a sustainable maintenance programme as good.
- NFSD is unlikely to replicate its very intensive involvement in the Sri Lankan Anti Leprosy Campaign in more than a very few countries because of the substantial human, financial and other resource costs involved. But WHO Geneva confirms the view that innovative approaches developed in Sri Lanka with NFSD support were trend-setting and paved the way for solutions that have been adopted by many countries.
- There is a strong case for making an application for free anti-TB drugs from the Stop TB Partnership's Global Drug Facility (GDF).[1] The health infrastructure in Sri Lanka, combined with the overall community awareness, hold potential for making a definite impact on the incidence of the disease in the country. However, it is likely to have greater impact if it is combined with, or complemented by, an awareness programme to reduce the still prevalent social stigma. The lessons from the Anti Leprosy Campaign are very relevant. Because of the synergies with leprosy, NFSD has made clear its intention to offer the Sri Lankan Department of Health Services a package of support for social marketing, training etc, under its drug donation agreement with WHO, if the government successfully applies to the GDF. The availability of donated drugs and the offer of wider support are both likely to be of real benefit to Sri Lanka.

[1] An application has subsequently been made to the GDF (August 2004).

Annexes

Annex 1. Study Terms of Reference
Annex 2. List of interviewees
Annex 3. The Anti Leprosy Campaign in Sri Lanka
Annex 4. The Anti Filariasis Campaign in Sri Lanka
Annex 5. Ministry of Health structure
Annex 6. Bibliography
Annex 7. Compliance with Interagency Guidelines for Drug Donations

ANNEX 1

Study Terms of Reference

Impacts of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries

Summary

The Initiative on Public-Private Partnerships for Health, in association with the Institute for Health Sector Development, proposes an extension (Phase II) of its previous work, the purpose of which would be to:

- Conduct a further three country studies of drug donation or discounted pricing programmes in low-income countries, in particular to evaluate their operations, and health and health system impacts. Countries proposed for such studies are Botswana, Sri Lanka and Zambia, on each of which a detailed report will be prepared;
- Prepare a synthesis of findings, conclusions and recommendations across all countries and programmes, including those studied in the Uganda Pilot Study; and
- Disseminate these reports to a range of relevant audiences.

Background

The health consequences of poverty lead to major health inequities for poorer populations in developing countries. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled by public sector or NGOs independently.

In recent years, a number of collaborations have arisen to tackle specific problems. These are usually targeted to specific products, diseases or technologies.

One particular group of these public-private partnerships (PPPs) addresses access to pharmaceuticals (usually drugs) that are critical to treatment or care for tropical diseases which disproportionately or uniquely affect the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated, heavily discounted or in some way subsidized by their producer (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications. These access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis, trachoma and sleeping sickness compared with HIV/AIDS, tuberculosis, and malaria). They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide.

Other types of public-private partnership have been established to encourage pharmaceutical companies to reduce the prices of (and sometimes donate) drugs which treat diseases which at least to some extent affect the citizens of both rich and poor countries – for example, HIV/AIDS and malaria. Here, the multi-partner initiative generally focuses on negotiating different (or tiered) prices across markets – with the most preferential prices reserved for public sector services in developing countries which are assumed to be accessed by the poorest. These types of initiative have generated more controversy due to the difficulties of establishing what are considered to be 'fair' prices in different markets and the problem of arbitrage – or leakage between those markets. Furthermore, they are more difficult than the drug donation programmes above to classify as 'PPPs', since they are not necessarily distinct from normal government purchaser-pharmaceutical provider contracting processes (such as bulk purchasing arrangements) and are heavily influenced by the presence (or not) of generic equivalent products in the market.

Both types of public-private partnership raise a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key question is the degree to which

the involvement of multinational R&D pharmaceutical companies in some stage of drug supply/procurement and delivery facilitates better drug availability and access by the poor. Further questions include whether the availability of free/reduced price drugs distorts decisions on priorities or prices and what the feasibility is of taking such initiatives to scale, and their sustainability. This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of debt relief, Sector-Wide Approaches (SWAps) in health, and multi-sectoral Poverty Reduction Strategic Plans (PRSPs). Issues of integration, coordination, implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

The UK Department for International Development (DFID) is funding the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct a series of studies across a range of access partnerships and countries.

Phase I: Pilot study in Uganda, 2003 (completed)

A pilot study to assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals in a selected low-income country was undertaken in Uganda in May 2003. It covered tropical disease programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness, and three HIV/AIDS PPPs: the UNAIDS Drug Access Initiative/Accelerated Access Initiative, the Viramune Donation Programme and the Diflucan Partnership Programme. The study also pilot tested a study protocol and research instruments for further studies. A full report on the pilot study is available.

Phase II: Three more country studies, a synthesis paper and dissemination

DFID is now funding IPPPH to:

- **Undertake three further country studies** including at least two studies of HIV/AIDS PPPs and two of selected tropical disease PPPs. The countries – Botswana, Sri Lanka and Zambia – have been selected to ensure that, together with the Uganda study, the maximum number of global drug access partnerships is examined, including major active tropical disease partnerships. The study in Sri Lanka will specifically examine whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.
- **Examine supranational level issues** including how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate, and how they relate to the countries examined.
- **Prepare a synthesis paper** of all the work and conclusions, including the pilot study. The purpose of the synthesis paper is to compare and contrast for policy makers the potential implications, cost, benefits, and risks of drug donations and discounted pricing schemes for contributing to expansion of access to appropriate treatment or control of diseases that primarily afflict poor populations. The synthesis shall also note for policy makers, pharmaceutical companies, and other actors (such as NGOs or funders) operational options that can maximize health and health system benefits and reduce any potential undesirable impacts of such arrangements.
- **Develop and implement a dissemination strategy**, which will communicate the key findings, conclusions and recommendations of the studies to a range of relevant audiences including national policy makers, bilateral and multilateral aid funders, pharmaceutical companies and non-governmental agencies.

Objectives

The specific objective of the current studies is to assess the health and health systems impact in the selected countries of public-private partnerships for improving access to pharmaceuticals in relation to HIV/AIDS and to tropical diseases, where pharmaceutical companies are involved as partners at some stage of programme design and/or implementation.

The studies should map the key features of the PPPs, and examine the relationship between the specific drug donation or discount price programmes, the broader partnerships in which they participate and the countries examined.

At country level, the studies will examine issues of ownership, regulation, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured (for example, the World Bank's MAP, the GFATM or generic purchasing activities). They will review the PPPs in relationship to country health systems and the broader context, both vertically (e.g. how the PPPs relate to pharmaceutical policies, donor/funding issues, broader partnerships) and horizontally (e.g. perceptions and impacts of the partnership from both PPP and government perspectives).

Key issues for examination should include:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.
- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available on the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and MIS/HMIS; government-NGO working relationships.
- For anti-retro viral drugs (ARVs), the effects of different models of drug supply on regulation, drug procurement and drug distribution. In addition, their impact on equity of access and product availability/prices in both public and private sectors.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

Outputs

The outputs for the country level work in this second phase of activity will be individual reports on the three further country studies.

Methods

Rapid assessments: These are rapid assessments rather than detailed studies. Documentary, quantitative evidence should be obtained wherever available. However, it is recognised that these are likely to be largely qualitative studies making extensive use of semi-structured interviews with key informants. Given funding and time limitations, the studies will not undertake significant original data gathering.

Country studies: The precise range of programmes will vary from country to country.

Fieldwork in each country will be undertaken in a two-week visit by a team of international and national consultants. Undertaking the work in a two-week visit will require effective pre-visit preparation and the prior development of base documentation on the country context and the individual PPP/programmes.

The country studies should adopt a layered approach to evaluation, covering the country context and the disease control policy before assessing the individual partnership programmes. Fieldwork will include interviews about each programme at national, regional (where appropriate), district and health facility levels. Criteria for selection of districts should include:

- Active implementation of those PPP programmes being studied, ensuring that each pro-

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gramme is visited in at least one district. HIV/AIDS programmes should be examined in the capital and at least one contrasting district.

- Regional and socio-economic representation.
- Security and accessibility, within the timescale of the study.

Fieldwork should include interviews about each relevant programme at national, regional (where appropriate), district and health facility/community levels.

ANNEX 2

List of interviewees

Dr H A P Kahandaliyanage, Director-General of Health Services
Dr A Mendis, Deputy Director General for Laboratory Services
Dr T Liyanage, Director, Anti Filariasis Campaign
Dr S Settinayake, Director, Anti Leprosy Campaign
Dr N D Kasturiaratchi, Consultant to the Anti Leprosy Campaign and Senior Lecturer, Medical Education, Faculty of Medicine, Peradeniya
Dr H Benaragama, Director, Medical Supplies Division
Mr E D Weeraratne, Senior Pharmacist, Medical Supplies Division
Dr P Fernando, Consultant, Anti Malaria Campaign
Dr I Abeywickrema, Director, National STD/Aids Control Programme
Dr C Sarukkal, Director, National Programme for TB Control and Chest Diseases
Dr K Sooriyaarachchi, Medical Officer Planning and Advocacy, National Programme for TB Control and Chest Diseases

Dr W D H Perera, Consultant Dermatologist, Colombo
Dr A L A L Padmasiri, Deputy Provincial Director of Health Services, Gampaha District, Western Province
Dr B P Mallikarachchi, Regional Epidemiologist, Gampaha District
Mr K Fernando, Divisional Pharmacist, Gampaha District
Mr J Perera, Public Health Inspector Leprosy, Gampaha District
Dr P Dissanayake and staff in OPD and the Pharmacy at the Kandy Teaching Hospital
Dr P Tennekoon, Medical Officer, Warakapola District Hospital

Dr Kan Tun, WHO Representative, Sri Lanka
Ms Kumudini, WHO Country Office
Dr Derek Lobo, Medical Officer, Leprosy, SEARO
Dr H Endo, Director, Department of Control, Prevention and Eradication, Communicable Disease Programme, WHO Geneva
Dr D Daumerie, WHO Group Leader Leprosy Elimination, Geneva

Mr J Sellahewa, DFID Sri Lanka

Dr L Jayasuriya, GlaxoSmithKline Medical Adviser, Sri Lanka
Mr A Kumar, Director, ABC Pharma, Colombo
Mr A Banayake, ABC Pharma, Colombo (ex-Head of Ciba Geigy, Sri Lanka)

ANNEX 3

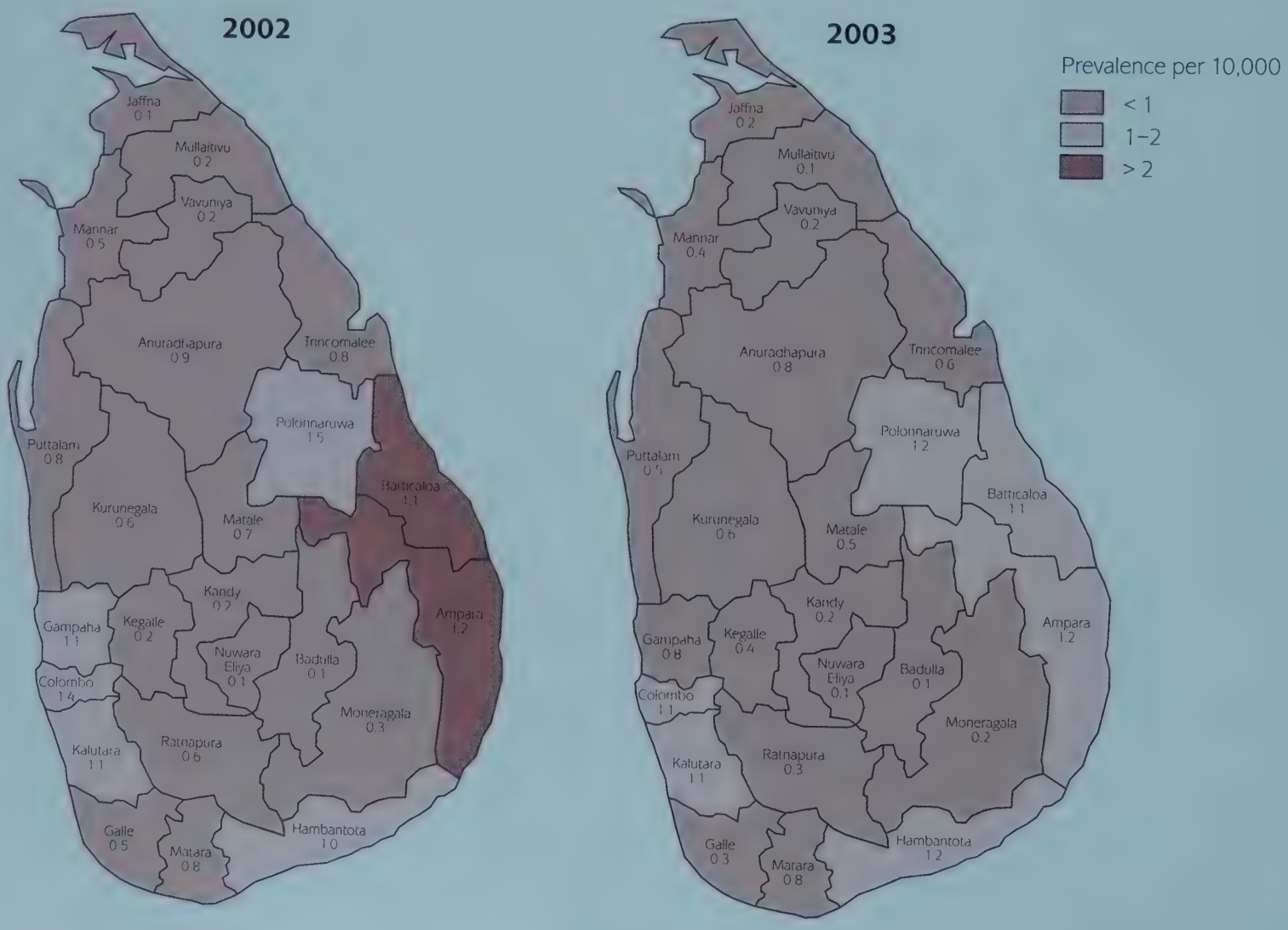
The Anti Leprosy Campaign in Sri Lanka

Leprosy is a chronic infectious disease caused by a bacterium and mainly afflicts the skin and peripheral nerves. The microbe, *Microbacterium leprae*, was identified in 1874 and ironically although the disease was one of the first bacterial diseases to be identified, it was one of the last to be curable (Fishlock, 1994). There are two main kinds of leprosy: paucibacillary (PB), a milder type which usually cannot be transmitted and can now be cured in six months of regular monthly multidrug therapy (MDT), and the more serious and infectious multibacillary (MB) which takes 12 months treatment though the patient is no longer infectious after only 4–6 weeks of treatment. Historically leprosy patients have additionally suffered acutely from stigma and segregation.

In 2002, leprosy was endemic in seven districts of four Provinces in Sri Lanka: all three districts in Western province (including Colombo), two in the conflict-affected Eastern Province, and one each in North-Central and Southern Provinces. By 2003, one further district had achieved elimination and no district had a prevalence greater than 1.2 per 10,000 inhabitants.

A long-standing history of leprosy control

Sri Lanka's history of leprosy control dates back to Dutch colonial times when in 1708 a leprosy asylum – probably the first of its kind in the East – was established at Hendala. For nearly three centuries, segregation of patients was the main mode



of control, with legislation to enforce segregation in 1901 and a second leprosy asylum established in 1920. Despite the introduction of Dapsone monotherapy in the 1940s, compulsory admission of patients to leprosy hospitals continued until 1977; from then on, non-infectious patients were treated at home. Admission stopped completely with the introduction of MDT in 1982 but patients admitted before then still remain in the two leprosy hospitals. Government policy is to look after ex-patients for the rest of their lives.

In 1954 the Anti Leprosy Campaign (ALC) was established in the Ministry of Health as a vertical governmental campaign to plan, coordinate and evaluate leprosy control activities in the country.

The period from 1970–1990 saw the strengthening of field activities, beginning in 1970 with the appointment in each district of one full-time trained paramedical worker – the Leprosy Public Health Inspector (PHI). They were engaged in conducting clinics, village surveys, contact surveys, default retrieval and educational programmes. From 1970 until integration into the General Health Service in 2001, the Anti Leprosy Campaign operated through these 25 specially trained PHIs working in districts, with only three medical officers at the central level. In the Gampaha district visited by the study team, the leprosy PHI had handled 99% of cases on his own, referring only 1% to a doctor. NFSD funded additional allowances for PHIs in recognition of their responsibilities for diagnosis and treatment, as well as transportation. These allowances have been lost with integration and the PHIs' loss of clinical responsibilities.

Multi Drug Therapy

Multi Drug Therapy (MDT) did not begin in Sri Lanka with the Novartis Foundation donation or the global WHO programme. It was introduced by the Anti Leprosy Campaign as the standard treatment for all registered patients in 1982, with financial and material help from the Leprosy Relief Work Emmaus, Switzerland (Emmaus). Sri Lanka was the first country in Asia to do so. In 1988 the Novartis Foundation for Sustainable Development (NFSD) joined with Emmaus in providing technical, financial and material support to the ALC. From that date Novartis or the Foundation has provided MDT for all leprosy patients in Sri Lanka in blister packs. Initially NFSD supplied MDT direct to the Ministry of Health, but since a 1999 Novartis agreement with WHO to donate MDT to all endemic countries (see paragraph on the international partnership below), supplies for Sri Lanka have been routed via WHO.

The donated MDT is a combination of Lamprene ® (clofazimine), Rimactane ® (rifampicin) and dapsone in four types of blister packs (adult and child packs for both PB and MB forms of leprosy).

Social marketing

Despite the free availability of MDT, transmission continued at around 1,000 new cases a year, of whom 15–20% were children. This clearly showed that substantial numbers of hidden cases were not being recognised.

In her Administration Report for 1988, the then Director of the Anti Leprosy Campaign remarked: "A change in the attitude towards leprosy is required to make a real difference to the leprosy situation in Sri Lanka. Consequently the only viable option is to launch a social marketing campaign in order to destigmatise leprosy, create an awareness of the early signs of the disease and encourage patients to seek treatment".

The ALC and NFSD developed and implemented an innovative social marketing campaign – run by a private advertising agency – to detect and treat the hidden caseload (i.e. people infected with leprosy but not on treatment). Launched in 1990, this involved using the mass media to encourage people to seek treatment, and improving access to treatment. NFSD spent about £250,000 on radio, television, press and poster advertising, and specially commissioned programmes with the message that leprosy can be cured (Fishlock 1994). Opinion formers in Sri Lankan society – priests, doctors, village elders, school teachers – were targeted, and children proved a particularly receptive audience. The aim was to banish all stigma, show how easily leprosy can be spotted, and create spontaneous public demand for diagnosis and treatment.

At the same time the number of field clinics was increased from 76 to 210 to provide easier access. Strong links were forged with regional health authorities and with dermatologists. All preventative health staff were trained to detect and refer cases of leprosy, and given pocket calendars with dates, times and locations of clinics. Week-long sessions with teledramas, education and training were held in remote areas.

A WHO report, *Leprosy: Learning from Success* (WHO, 2001), reports that the results of the campaign were spectacular. In less than a year case detection increased by 150%. Self-reporting went up from 9% in 1989 to 50% in 1991, and has remained high since. The campaign is generally regarded as having been the most successful of its kind in Sri Lanka. There is scope for the lessons to be applied in other programmes. For example, TB has liaised with ALC in preparing to launch its own social marketing campaign in April 2004.

Disability care

Since 1991, NFSD has also been providing technical expertise and financial assistance to facilitate the physical and economic rehabilitation of leprosy-affected people, including through training of surgeons, leprosy health inspectors and physiotherapists. For example, before 1992 leprosy patients with deformities did not have easy access to physiotherapy units or surgical clinics, ostensibly because of overcrowding and priority being given to service personnel injured in conflict areas, but in part at least because of stigma among staff. Given the encouraging results of the social marketing campaign, it was decided to provide comprehensive care for the neglected new and old deformity patients with NFSD support.

NFSD have sponsored regular quarterly visits to Sri Lanka by Dr Atul Shah (plastic surgeon) and Mrs Neelah Shah, who have wide experience in deformity care in India, to prepare and implement a plan to provide comprehensive services to leprosy patients with deformities. Most early deformities were corrected using his innovative, user-friendly devices; reconstructive surgery was performed with local orthopaedic surgeons; ulcer camps were held in 18 districts to train ulcer patients in self-care; and physiotherapists in endemic districts were trained in management of deformities. Initially, shoes and splints were made in India but now NFSD funds products from a specially trained local cobbler.

On integration into the General Health Service, all physiotherapists attached to government health institutions were trained between 2002–2003. About 10% of new patients each year require restorative and rehabilitative care.

Integration into the General Health Service and mode of operations

Throughout this period, the vertical structure of the Anti Leprosy Campaign with its dedicated team able to take swift decisions achieved impressive results. Elimination of leprosy, defined by WHO as less than one patient for 10,000 inhabitants, was achieved at the national level in Sri Lanka in 1995, five years ahead of the original WHO target of 2000 (now extended to 2005).

However, as prevalence dropped so markedly, a new more cost-effective approach was needed since PHIs were travelling long distances to hold field clinics with few or even no patients. Moreover, a consequence of the existence of a specialist Anti Leprosy Campaign was that the country's curative health facilities did not consider leprosy to be their responsibility. In 1999, despite some hesitation about tampering with a smooth running service, the Sri Lankan health authorities decided to integrate leprosy services into the general health services (Kasturiaratchi 2002).

The vision of the integrated programme was to reduce leprosy and its related distress by reducing the reservoir of leprosy sustainable and by improving the quality of life of people affected by leprosy. The general objective was to reach the elimination target at subnational level in remaining endemic areas, with the integration of elimination activities into the general health services.

Under the integrated system, a patient can turn to any curative health facility or dermatological clinic in the country, or to the ALC's Central Leprosy Clinic, and receive MDT. Monthly follow-up doses of MDT can be obtained directly from the pharmacist on presenting the patient MDT card if the patient does not wish to see a doctor. Complications that cannot be managed by the health facility are referred to the closest dermatological clinic or the Central Leprosy Clinic.

Private practitioners can obtain MDT free of charge directly from the Central Leprosy Clinic but private hospitals have not yet been supplied. NFSD provided encouragement and support for training of private clinicians but there was little interest; currently only three of them take advantage of the offer of free MDT.

The regional epidemiologists were identified as the 'managers' of the integration process together with the leprosy PHI for each district who was no longer to treat general leprosy patients. The main roles of

the leprosy PHI are now to assist the Regional Epidemiologist in the compilation of data, monitoring of returns and MDT status of health institutions, and providing services to deformity patients. In most districts they also undertake other activities, such as rabies, TB and malaria control, and supervise other PHIs since they tend to be senior.

The new role of the Anti Leprosy Campaign under integration was to:

- Provide technical guidance to provincial level programme managers
- Upgrade the central referral clinic (the central leprosy clinic) offering specialised services
- Train medical students, post graduate trainees and other health categories attached to training centres of the Ministry of Health
- Provide anti-leprosy drugs (MDT) to the provinces (until end 2003: see below)
- Monitor the national programme
- Formulate national policy and assist preparation of district plans
- Disseminate new information to relevant staff
- Coordinate with the Colleges of Dermatologists, Community Physicians and Health Administrators on training and policy issues.

The actual process of integration posed some major planning, operational and change management challenges and was supported by the Novartis Foundation. It entailed amongst other things reorienting and motivating large numbers of doctors and other staff in some 1,000 health institutions, producing a special leaflet for Ayurvedic practitioners on leprosy recognition and referral, and a formidable logistical operation to supply all health facilities with MDTs and other supplies such as specially designed patient forms and registers, patient information and posters. In Gampaha all school teachers were trained to recognise the symptoms. Again a professional advertising campaign was used to create awareness of the availability of treatment at all health facilities as well as overcome residual stigma attached to leprosy. A special campaign was developed for the Tamil community in Sri Lanka, and a 'think leprosy' campaign targeted health care providers.

Integration was formally launched in February 2001. Contrary to some concerns about the likely epidemiological impact that the focus will be diluted and that more cases will be missed, the prevalence actually increased by 36% and new case load that was identified also increased by 41% (corrected for about a 5% re-registration rate).

Only 20% of health institutions (mainly major hospitals) reported new leprosy cases in the first two years after integration. Nonetheless, with strong encouragement from WHO, at least small stocks of MDT are maintained at all health units in line with the policy to increase the accessibility of MDT, especially in low endemic situations.

The distribution of MDT continued to be handled centrally by the ALC until 2004 when responsibility passed to Medical Supplies Division (MSD) for receipt of the drugs from WHO, storage at both central and regional level, and island-wide distribution. The District Leprosy Team consisting of the Regional Epidemiologist and the PHI, assisted by ALC, coordinates the distribution. The four types of MDT (PB adult, PB child, MB adult and MB child) are now line items in the Annual Drug Estimate books issued to all health institutions, providing MSD with estimates of drug requirements. Buffer stocks are held in district drug stores and by PHIs.

Activities in the North East

Leprosy elimination activities are said to have continued "without much interruption" during the unsettled period through the Leprosy PHI for Jaffna and Kilinochchi (Settinayake, 2003). The International Committee of the Red Cross and Médécins sans Frontières ran general mobile field clinics in two districts, and were supplied with MDT by the PHI. After the Memorandum of Understanding between the Government of Sri Lanka and the Liberation Tigers of Tamil Eelam in 2002, migration of people to the conflict-affected areas increased and mobility improved. Development activities accelerated. On the leprosy front, in order to strengthen the integrated approach, a comprehensive plan of action for the North East was prepared and is currently being implemented with support from the Novartis Foundation and a consultant to the ALC. Alongside training and logistical activities, educational materials have been prepared in consultation with provincial health authorities. This social marketing campaign exclusively for the North East is about to be launched, using information brochures for patients and health workers, posters, billboards in Tamil and radio spots on national and regional radio stations. Additional

stocks of MDT have been issued to districts to meet expected increased demand. Continued support for the North East is a core priority for the Novartis Foundation.

Current progress

The challenge now is to secure elimination at subnational level. Against the WHO definition of the elimination of leprosy as less than one patient for 10,000 inhabitants, the overall national prevalence rate in 2002 was 0.8 per 10,000 inhabitants. However, five districts still had rates of 1–2 per 10,000, and two districts in the conflict-affected Eastern Province had rates of 3.0 (Batticaloa) and 2.7 (Ampara). New figures for 2003 show that the national prevalence rate has dropped to 0.68 patients per 10,000 and one further district (Gampaha) has achieved elimination. Rates in Batticaloa and Ampara districts have fallen to 1.1 and 1.2 respectively. No district had a rate above 1.2 per 10,000 inhabitants.

Figure 1 below demonstrates the trend between 1985 and 2002. The long (24-month) duration of MB treatment is one of the reasons for high prevalence prior to 1987. Cleaning the registers was completed in 1987.

Both prevalence and new case detection rates (per 10,000 population) registered increases in 1990 with the social marketing campaign, and 2001 with the integration of leprosy services into the general health services and its accompanying public campaign (Figures 1 and 2).

Child and deformity rates are also key indicators. Child rate is the percentage of total newly detected cases found among children under 15 years. Any case of a child with leprosy is followed up with a home visit to other household members. In Gampaha district all schoolteachers have been trained to recognise the symptoms of leprosy.

The Deformity Rate is the percentage of newly-detected cases where patients present with deformities, (i.e. they present late). The 1991 change in trend marks the start of NFSD's provision of the services of Dr. Atul Shah, Director, Comprehensive Leprosy Care Project, Mumbai, India to reorganise the deformity care services within the Sri Lanka Anti Leprosy Campaign. Subsequently, specialists and physiotherapists of the General Health Service were trained in deformity correction and management respectively.

Figure 1. Leprosy prevalence 1985–2002

Figure 2. Leprosy new case detection rate 1985–2002

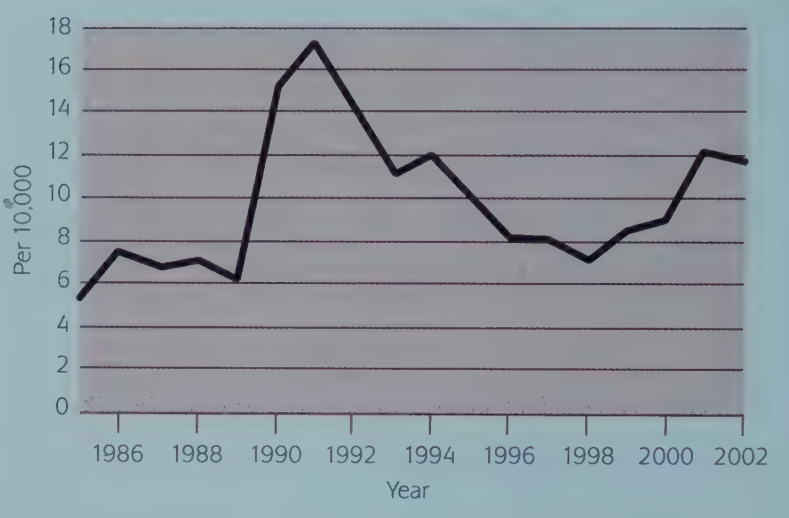


Figure 3. Leprosy child rate 1985–2002

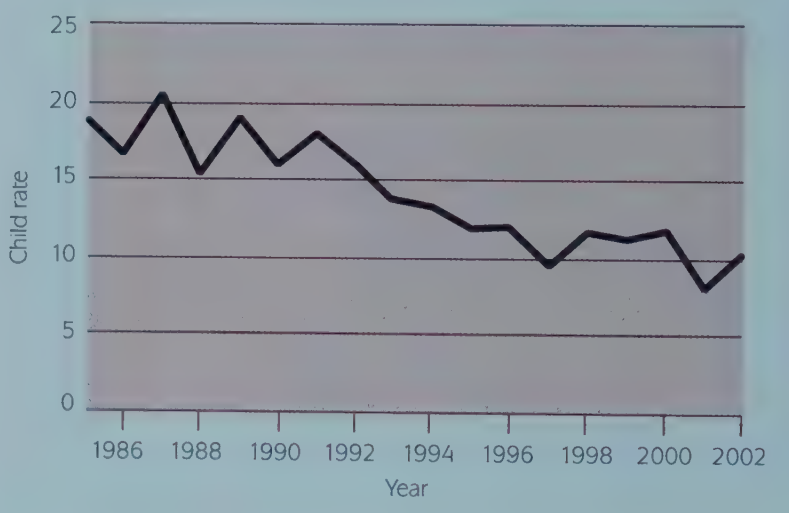
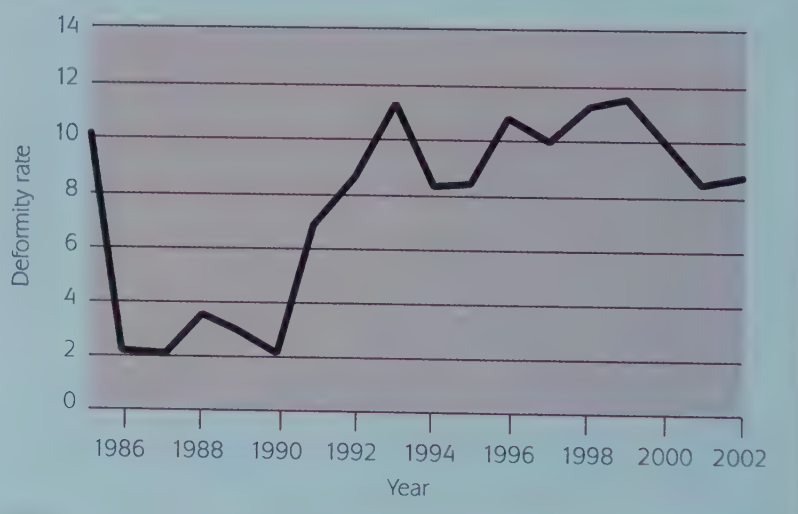


Figure 4. Leprosy deformity rate 1985–2002



The international partnership

In May 1991, the World Health Assembly adopted Resolution WHA44.9 declaring the year 2000 as the target date for achieving the global elimination of leprosy. Between 1995 and 1999, WHO, with support from the Nippon Foundation/ Sasakawa Memorial Health Foundation of Japan, began providing free MDT drugs to national leprosy control programmes with the objective of achieving this global target. Sri Lanka did not participate in this programme since the country was already receiving free MDT from the Novartis Foundation.

While significant progress towards the global elimination target was realised, it became evident that elimination would not be achieved by all countries within the target date. The WHA resolved to put into effect an accelerated plan (the 'Final Push') for elimination by 2005. In November 1999, on the initiative of WHO, the Global Alliance for the Elimination of Leprosy was formally created with the aim of "ensuring that all patients, wherever they may be, will have free and equal access to the most modern treatment available". The partners were the endemic countries, the Nippon Foundation, Novartis, DANIDA and WHO.

In that same year, WHO signed a Memorandum of Understanding with the Novartis Company for the donation in kind of free MDT drugs over the period 2000–2005 in pursuit of the "final push" to achieve global elimination. The Nippon Foundation/ Sasakawa Memorial Foundation provided an additional US$ 24 million as operational support for the final push. DANIDA and the World Bank also work closely with GAEL. Novartis' agreement for the free supply of MDT is to be extended to 2010 to achieve and sustain elimination. WHO has also negotiated with Novartis a donation of clofazamine alone to treat severe ENL reactions.

In 2002, Novartis reappraised its MDT blister design and packaging to improve resistance to environmental heat, moisture and damage in the field as well as making the treatment more patient friendly. This involved substantial new investment costs for Novartis.

WHO undertakes quality assurance of the donated drugs both through batch testing and testing samples collected from the field. Novartis provides WHO with 9% of the value of the drugs shipped in any given year, in advance, to cover the costs of quality assurance, logistics and insurance.

By the end of 2002, leprosy remained a public health problem at national level in only 12 countries, and the number of cases registered had been reduced by almost 90% since 1985 when MDT started being introduced on a global scale – from around 5.4 million to less than 0.53 million.[1] The WHO Technical Advisory Group for the Elimination of Leprosy has been addressing issues related to the final push including: easier serological diagnostic tools for leprosy; simpler treatment regimens including new drugs and drug combinations; accompanied MDT to improve cure rate; uniform MDT for all types of leprosy; and the validation process for elimination. The TAG has recommended that a formal certification process for elimination would be both expensive and unnecessary and should not be pursued by WHO.

While the free supply of MDT drugs and clofazamine remains of considerable benefit to Sri Lanka, the Global Alliance itself has been of less importance since the country had been receiving free drug supplies since 1982, together with substantial operational support. Since national elimination was achieved in 1995, Sri Lanka was not invited to any GAEL events, though NFSD sponsors the Director of the Anti Leprosy Campaign to attend the International Leprosy Congress every four years.

[1] *WHO Leprosy Elimination Project, Draft Annual report 2003 and MDT Needs for 2004*, WHO Geneva November 2003

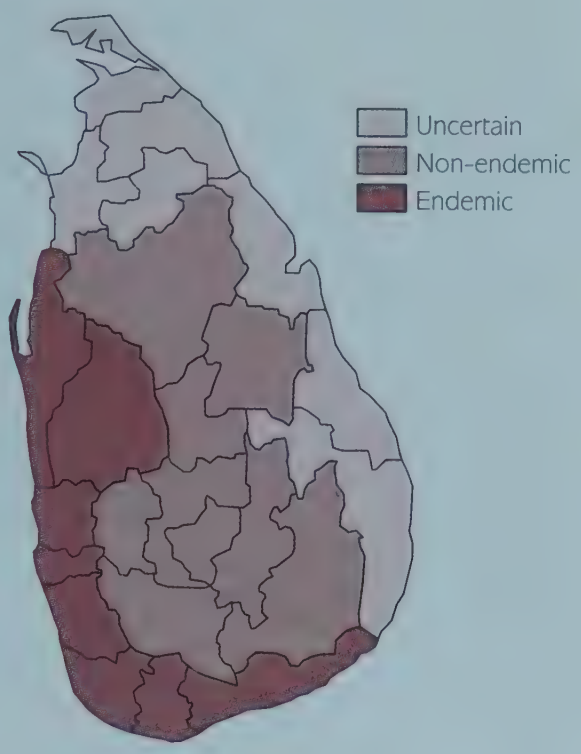
ANNEX 4

The Anti Filariasis Campaign in Sri Lanka

Lymphatic Filariasis (commonly known as elephantiasis) is a painful and profoundly disfiguring disease that has a major social and economic impact in Sri Lanka, having a high morbidity with no mortality. The only insect vector responsible for the spread of urban filariasis in Sri Lanka is the *Culex quinquefasciatus* mosquito. It breeds in highly polluted collections of water, such as blocked drains, damaged septic tanks, latrine pits etc which abound in urban habitats.

Filariasis is endemic in eight districts of three provinces (Southern, Western and North Western). It is mainly seen in these areas due to rapid and unplanned urbanisation. In total, 9.8 million[1] people – half the country's population – are at risk. The migration of people to and from the endemic zone has resulted in spreading the disease to other areas as well. There is low level transmission in most of the non-endemic areas. The position in the conflict-affected North-East affected is uncertain.

Distribution of lymphatic filariasis



[1] According to the 2002 Census. Figures from Provincial Health Authorities amount to 10.04 million.

The international partnership

In 1997 a World Health Assembly resolution called for countries "to strengthen activities towards elimination of lymphatic filariasis as a public health problem". The following year GlaxoSmithKline (GSK) and WHO signed a Memorandum of Understanding covering among other things the donation of all the albendazole required for the LF elimination programme. The value of the albendazole donated globally by GSK between 1999 and 2002 is estimated at US$ 13.6 million at wholesale acquisition cost. In 1999 the Mectizan ® Donation Programme of Merck & Co expanded its existing donation of Mectizan ® (ivermectin) for onchocerciasis to the treatment of LF in African countries where the two diseases co-exist. This is not relevant in Sri Lanka where there is no onchocerciasis and ivermectin is not registered for use in humans.

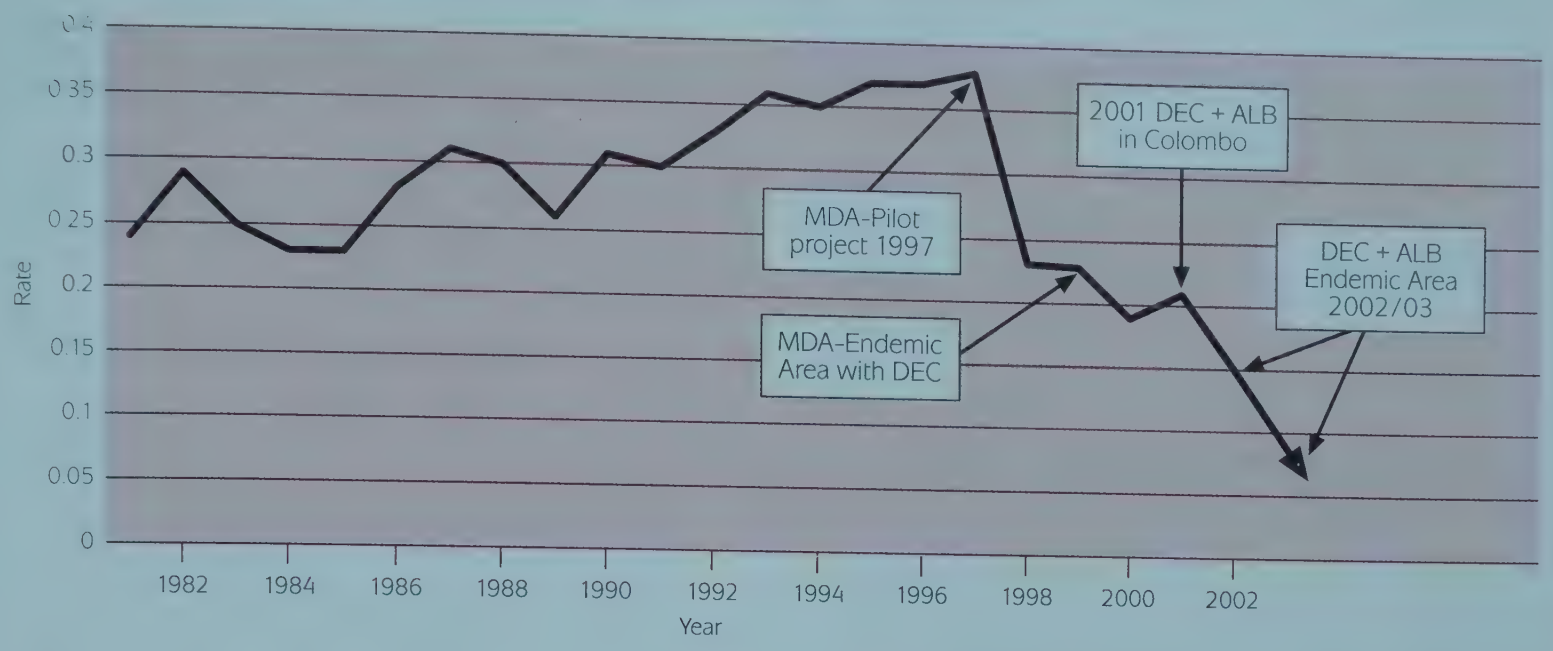
The Global Alliance for the Elimination of Lymphatic Filariasis (GAELF) was established in May 2000 and is envisaged to last at least until 2020.The secretariat is provided by the LF team in WHO, and technical and operational decisions remain the responsibility of WHO. GAELF's global target for 2005 is coverage of 350 million people at risk. Sri Lanka participates actively in the Global Alliance.

Programme objectives and strategies in Sri Lanka

Goal and objectives

The Anti Filariasis Campaign (AFC) of the Ministry of Health has as its goal the elimination of Lymphatic Filariasis as a public heath problem by 2010, measured by the WHO standard of a microfilaria rate of 0.1%.

Figure 5. Microfilaria Rate from 1981–2002



Its objectives are:

- To stop the spread of filarial infection (i.e. the interruption of transmission)
- To alleviate the suffering and disability of affected individuals
- To develop a database for monitoring and evaluation of the control programmes.

Strategies

The strategies and control measures adopted by the AFC are:

- Parasite control through screening of the population annually by night blood screening and treating the positives with diethylcarbamazine (DEC) until they are free of infection. Currently 10% of the population at risk is being screened each year
- Once-yearly mass treatment of all eligible individuals in the endemic areas with a single dose of albendazole and DEC given together
- Vector control by eliminating breeding sites of the vector mosquitoes
- Morbidity control-lymphoedema management. Access to knowledge of self-care of lymphoedema and hydrocele surgery to all patients suffering from LF-relates clinical manifestations and disabilities.

Current progress

Morbidity

In 2003 elimination of LF as a public health problem was achieved at national level with a microfilaria rate of 0.09%. This marks a reduction from 0.15 in 2002 and 0.21 in 2001 (when there had been a slight increase due to detection of cases in some districts where active surveillance was strengthened).

However, in some small areas in the known endemic area, the rate in 2003 still exceeded 0.2%.

At this moment the AFC does not have reliable information on the incidence and prevalence of LF in the conflict-affected areas of the North and East. A mapping exercise has just begun and will provide a better picture by the end of 2004. Currently the campaign has a total of 16 patients from the North and East, eight of whom are refugee returnees from India (Tamil Nadu and Kerala).

Single dose mass treatment campaign

A single dose mass treatment campaign began in 1997 as a pilot in selected areas of Sri Lanka. The national programme for the eight districts comprising the entire endemic area was launched in 1999 with mass drug administration (MDA) using DEC. It achieved coverage of 62.7% of the target population as against the 80% needed. This approach was also followed in 2000.

For the MDA in 2001, seven districts continued to use DEC but a pilot in the Colombo district used a combination of albendazole and DEC. Children aged 2–12 years were given 150 mg of DEC, and people over 12 years old were given 300mg of DEC and 400mg albendazole irrespective of age. Children under two, pregnant and lactating women, and seriously sick people were excluded. Coverage reached 76.7%. A post treatment survey in Colombo of 2,000 individuals revealed no reports of serious side effects.

Since 2002, the approach is for annual MDA of the entire endemic area using the combination of DEC and albendazole in single doses. The State Pharmaceutical Manufacturing Corporation provides the DEC tablets, and the albendazole comes from the GSK donation via WHO.

In 2003, the MDA covered a population of 9.8 million and involved 50,000 filariasis prevention assistants for house-to-house distribution on a Sunday and mopping up for two weeks after, with the drugs being consumed in their presence. There was an intense social mobilisation campaign before and during the MDA, including a leaflet for every household, a media campaign by a private advertising company, promotional activities in schools and banners in towns and schools. An independent evaluation found an observed coverage rate of 88.4%. Coverage exceeded 80% everywhere apart from a few urban areas. The total additional cost of the 2003 MDA was 14.2 million rupees (US$ 147,783) or 1.45 rupees per person. The national contribution to this (excluding normal salary costs) was 6.06 million rupees to cover DEC, payments for health workers and other expenditure. WHO and the Liverpool School of Tropical Medicine LF Support Centre provided 8.13 million rupees for the social mobilisation programme and MDA (WHO pays the advertising company and printers direct). GSK donated supplies of albendazole were free.

Future plans

Future plans are to:

- Maintain the high coverage in the MDA programme for the next three years, and identify strategies to achieve high coverage in an urban setting
- Expand the provision of LF community home-based care, following a pilot
- Strengthen the morbidity control programme (surgical repair of hydrocele)
- Strengthen monitoring and evaluation using a standard Assessment, Monitoring and Evaluation Profile
- Strengthen vector control and establishment of PCR technique for efficient vector surveillance
- Conduct a pilot study on DEC medicated salt.

The main constraint is the lack of a proper data base system for efficient monitoring and evaluation of the programme at national level.

Governance and mode of operations

Filariasis control activities were decentralised in 1989. The main stakeholders in Sri Lanka are therefore the Anti Filariasis Campaign (AFC) directorate in the Ministry of Health, the Provincial health authorities, and the community at risk.

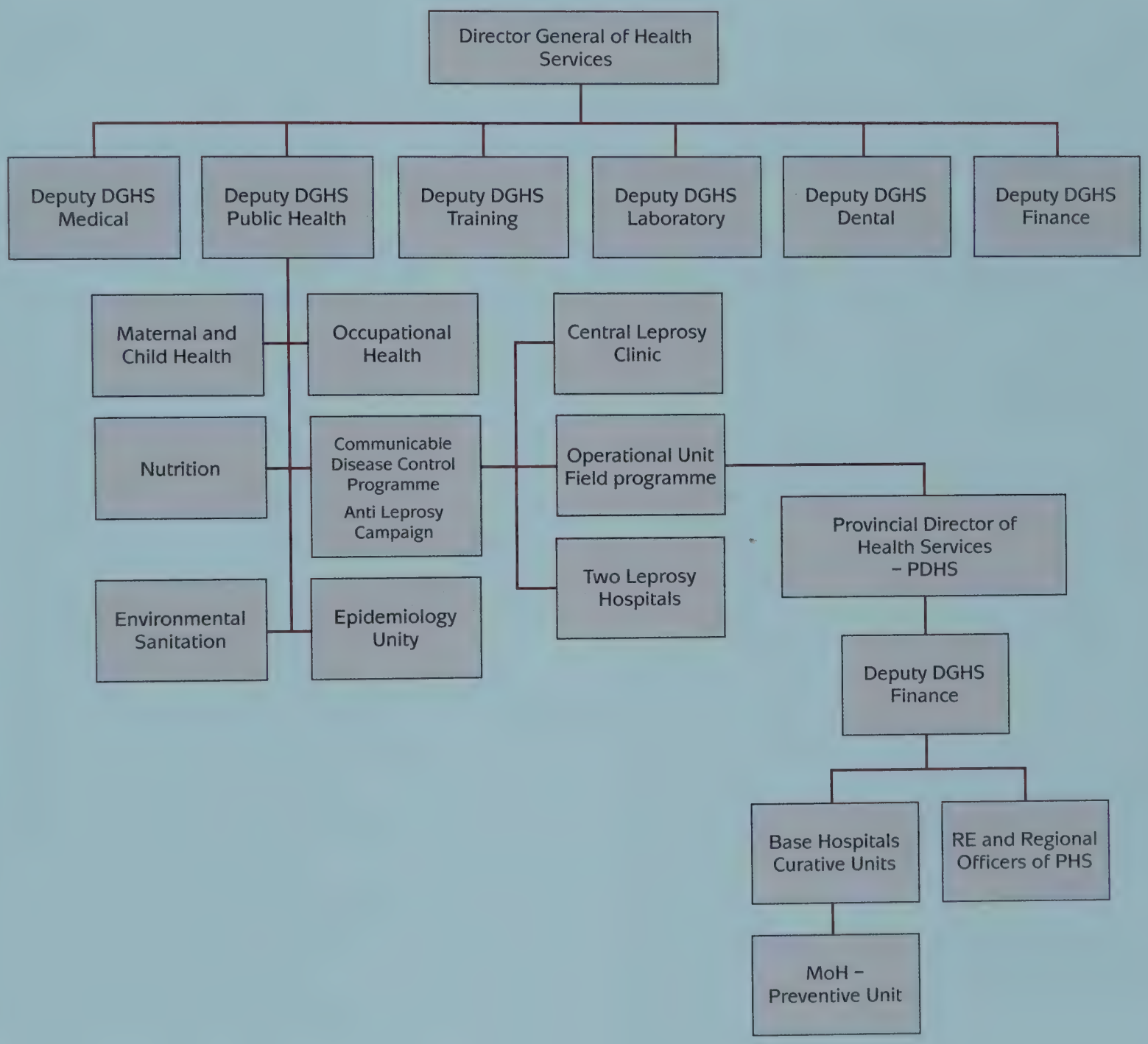
The AFC directorate has a staff of 35, including four medical officers. Its responsibilities cover:

- Preparing and implementing the National Plan to Eliminate Lymphatic Filariasis
- Monitoring and evaluating the filariasis situation country-wide
- Providing technical guidance to provincial filariasis control programmes.

At provincial level there are five dedicated medical officers to cover the eight endemic districts, plus public health inspectors. The responsibilities of the provincial health authorities cover planning, implementing and monitoring filariasis control within the framework of the national programme.

ANNEX 5

Department of Health structure in Sri Lanka



ANNEX 6

Bibliography

Sri Lanka context, health and health systems

National Health Bulletin 2001, Ministry of Health, Colombo 2002

Poverty Reduction Strategy Paper 2001, Government of Sri Lanka, Colombo, 2001

Regaining Sri Lanka: Vision and Strategy for Accelerated Development, Government of Sri Lanka, 2002

The Strategic Framework for Health Development, Ministry of Health, Nutrition and Welfare, Colombo, 2002,

Draft Strategy for a Healthier Nation, Ministry of Health, Nutrition and Welfare Sri Lanka, 2003

Master Plan Study for Strengthening Health System in the Democratic Socialist Republic of Sri Lanka: Interim Report, Pacific Consultants International, Colombo, 2002

Blazing a Trail in Macroeconomics and Health: The Sri Lankan Experience, Hon Sajith Premadasa, Deputy Minister of Health, Nutrition and Welfare, Sri Lanka (Presentation made at the Consultation on Macroeconomics and Health in Geneva, 2003)

Health System and the Health Needs of the North-East, Sri Lanka, World Health Organization, Sri Lanka, 2002

WHO Country Cooperation Strategy 2002–2005, World Health Organization, Sri Lanka, 2002

Leprosy

Settinayake S, *Leprosy Elimination Country Report*, Ministry of Health, Sri Lanka 2002–2003

Memorandum of Understanding between the Secretary of Ministry of Health acting for the Government of Sri Lanka and Novartis Foundation for Sustainable Development, May 2003

Department of Health Services General Circular Letter No: 02-157/2000: Integration of Leprosy Services To General Health Services, 13 November 2000

Department of Health Services General Circular Letter No: 02-158/2000: Statement on Integration of Leprosy Services To General Health Services, 13 November 2000

Department of Health Services General Circular Letter No: 02-159/2000: Integration of Leprosy Services To General Health Services, 13 November 2000

Department of Health Services Department of Health Services General Circular Letter No: 02-160/2000: Integration of Leprosy Services To General Health Services, 13 November 2000

Department of Health Services Department of Health Services General Circular Letter No: 02-165/2002: Integration of Leprosy Services To General Health Service and Distribution of Multidrug Therapy (MDT) Blister Packs to Institutions, 30 October 2002

Fishlock D., *Conquering leprosy through social marketing, Biologist* (1994) 41 (4), 146–148

Kasturiaratchi N D, Settinayake S and Grewal P, *Processes and challenges: how the Sri Lankan health system managed the integration of Leprosy Services, leprosy review* (2002) 73, 177–185

Perera J, *Evolution of the Elimination of Leprosy Gampaha District after Integration*, Western Province Ministry of Health, 2001–2003

Settinayake W A S and Herath H M S S D, *Leprosy Control in Sri Lanka, in Public Health Development in Sri Lanka*, Millennium Supplement of the Journal of the College of Community Physicians of Sri Lanka, 2001, ISSN 1391-3174, 64–55

WHO Leprosy Elimination Project, Draft Annual report 2003 and MDT Needs for 2004, WHO Geneva November 2003

Leprosy: Learning from Success, WHO Geneva 2001, WHO/CDS/CPE/CEE/2001.20

Lymphatic Filariasis

Annual Report for the National Programme to Eliminate Lymphatic Filariasis 2002, Sri Lanka

Reapplication for continuation or expansion of Programme to Eliminate Lymphatic Filariasis, Sri Lanka 2002

Reapplication for albendazole from the National Programme to Eliminate Lymphatic Filariasis, Sri Lanka 2003

Liyanage T, *The National Programme to Eliminate Lymphatic Filariasis*, Sri Lanka (PowerPoint presentation)

Global Programme to Eliminate Lymphatic Filariasis, Annual Report on Lymphatic Filariasis 2002, Ministry of Health, Colombo.

ANNEX 7

Compliance with Interagency Guidelines for Drug Donations

Checklist for compliance with Interagency Guidelines for Drug Donations, Revised 1999 (WHO/EDM/PAR/99.4) : Sri Lanka

	LEPROSY	LYMPHATIC FILARIASIS
All drugs should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent of the recipient	Y	Y
All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.	Y	Y
The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.	Y	Y
All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.	Y	Y
No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.	Y	Y
After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.	Y	Y
All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.	Y*	Y*
As much as possible, donated drugs should be presented in larger quantity units and hospital packs.	Y	Y
All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.	Y	Y
Recipients should be informed of all drug donations that are being considered, prepared or actually under way.	Y	Y
In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.	Y	Y
Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.	Y**	Y**

* All drugs imported are labelled in English in Sri Lanka.

** It is agreed that the government will clear from the port.

The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop and improve access to health products to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill & Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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